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Walden University

College of Health Sciences

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Haruna Ismaila Adamu

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2017

Abstract

Relationship Between Caregivers' Quality of Life and Childhood Tuberculosis in Nigeria

by

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MPH, Cardiff University, 1999

MBBS, Ahmadu Bello University, 1991

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

Walden University

November 2017

Abstract

In Nigeria, childhood tuberculosis (TB), a debilitating and deadly disease, is highly prevalent and case reporting is poor due to weak health systems. Globally, children account for at least 10 percent of the TB burden, yet they remain neglected in TB prevention and control efforts. Research studies integrating family and community-centered strategies have been recommended by stakeholders to address the paucity of current local prevention and management strategies for childhood TB. This observational cross-sectional study explored the relationship between caregivers' quality of life (QOL), gender, and socioeconomic status (SES) and the incidence of TB in children aged 0-14 years. Using the abbreviated version of World Health Organization's (WHO) QOL tool, the WHOQOL-BREF, data were collected individually in a face-to-face setting from caregivers ($n = 47$) whose children had been diagnosed with TB in Bauchi State, Northeastern Nigeria, over a 5-year period. Data were collected in the same manner from another set of caregivers of children without TB ($n = 47$) within the same period and setting. Results from logistic regression indicated a statistically significant relationship ($p < .001$) between the caregivers' QOL and the occurrence childhood TB. However, the caregivers' gender and SES were not significantly related to the incidence of childhood TB. This finding underscores the need to identify the factors that positively impact the QOL of caregivers of childhood TB cases. It also reflects the importance of integrating QOL interventions as part of TB control programs seeking to improve childhood TB reporting. This can mitigate the disease burden in vulnerable age-groups living in resource limited settings, thereby contributing to positive social change in the society.

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Dedication

To my late father, Alhaji Adamu Ismaila Kofar Naisa of blessed memory. May his gentle soul rest in perfect peace, amen.

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I thank Almighty Allah for making it possible for me to complete this doctoral process successfully. I remain grateful to my family: Jamila, Hadiza, Ahmad, Muhammad, Mahmoud, Hamidan, Adam, Ismail, Mustapha and Aisha for the unflinching love and support they gave me throughout the period of the course. I could not have succeeded without them being there for me all the time.

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Chapter 1: Introduction

Children accounted for 10% of the global tuberculosis (TB) burden in 2015 (World Health Organization [WHO], 2016a), yet they remained neglected relative to preventive responses to control TB. In addition, it is well documented that TB research, prevention, and control worldwide has predominantly focused on adults, neglecting children 0-14 years old (Daniel, Adejumo, Abdur-Razzaq, & Ebunoluwa, 2015; Erkens, de Vries, Keiser, Slump, & van den Hof, 2014; Hamzaoui, Yaalaoui, Tritar Cherif, Slim Saidi, & Berraies, 2014; Swaminathan & Rekha, 2010; WHO, 2013a). Furthermore, TB prevalence surveys conducted under the guidance of the WHO in the 21 global focus countries have excluded children aged 0-14 years. These are countries, identified by the WHO task force on TB impact measurement, where surveys of the prevalence of the disease are recommended (WHO, 2017).

However, children can no longer be ignored in TB research, prevention and control, as they accounted for 10% of the total global burden in 2015 (WHO, 2016a), 15% in South Africa (Bélard et al., 2015), 25% in Afghanistan (Nelson & Wells, 2004), 3.4% in India (Mukherjee et al., 2014), 7.9% in Peru (Chiang et al., 2015), 6% in Nigeria (WHO, 2015b) and 6% in the United States (Cruz & Martinez, 2015). The neglect of childhood TB (CTB) may explain the less than 10% proportions reported by some countries, including Nigeria. Over the past few years, clinicians and public health officials in these countries may have given less attention to diagnosis and treatment of TB in adults compared to children, resulting in under reporting of the true burden of the disease.

CTB burden is often underestimated by public health officials due to several reasons: the cases are mainly noncontagious (Hamzaoui et al., 2014), their diagnosis is difficult and often missed by clinicians leading to under-reporting (WHO, 2010), ignorance and stigma exist in society, and there is inadequate contact investigation and lack of access to laboratory tests and insufficient trained health manpower (Chiang et al., 2015). Furthermore, confirming the diagnosis of CTB in the laboratory can be very challenging due to difficulty in collecting sputum and other relevant specimens from infants and young children, and the tendency to have false negative results due to low sensitivity of the tests while trying to detect smaller number of bacteria in children (Centers for Disease Control and Prevention [CDC], 2014).

Thus, the diagnosis of CTB in many settings is confirmed on the basis of several criteria, namely: typical clinical signs and symptoms of the disease, positive purified protein derivative test (PPD), positive interferon gamma release assay (IGRA), typical TB chest x-ray patterns, and history of contact with an infectious TB case (CDC, 2014). Ultimately, the number of confirmed CTB cases determines the burden of the disease in a particular community, state, region, or country. This burden is likely to increase in regions of the world where adult TB is increasing, such as in sub-Saharan Africa (Nelson & Wells, 2004). TB control efforts include but are not limited to: strengthening of global surveillance of CTB, studying the roles of national TB programs (NTPs) in curbing the spread of CTB, and better identification of risk factors for CTB (Nelson & Wells, 2004).

Risk factors for the occurrence of CTB also vary by regions of the world (Nelson & Wells, 2004). Risk factors such as parents' or caregivers' nationalities, immigration

status, and race and ethnicity remain key in the occurrence of CTB in North America and Europe (Krogh, Surén, Mengshoel, & Brandtzæg, 2010; Nelson & Wells, 2004; Søborg et al., 2011). Socioeconomic risk factors such as poverty, crowding, and malnutrition were found to be associated with a greater risk of children developing TB in low and middle income countries (Stevens, Ximenes, Dantas, & Rodrigues, 2014; Nelson & Wells, 2004). In support of these observations, Nelson and Wells (2004) concluded “more studies are needed in low-income countries to examine specific risk factors for TB in children” (p. 641). Nigeria is one such country, because according to the World Bank (2016), the country is a lower middle-income country. This study, therefore, is a direct response to this recommendation and that of the WHO as presented in its proposed research priorities for CTB (WHO, 2007) and CTB roadmap (WHO, 2013b). Extensive literature review has shown that there is a paucity of research studies examining the relationship between CTB and variables pertinent to caregivers of young children in Nigeria. These include, but not limited to, caregivers’ quality of life (QOL), socioeconomic status (SES), and gender. QOL entails the way caregivers feel about their health and whether they get the support they need from others. It also involves presence of physical pain or a medical illness, how much they enjoy life, to what extent they feel their life is meaningful, whether they have enough money to meet their needs, whether they have opportunity for leisure activities, how satisfied are they with themselves, their sleep, their friends, daily activities, capacity for work, sex life, place of living, and how often they have negative feelings such as despair or even depression (WHO, 1994). Caregivers’ SES entails their educational status, income, occupation, access to improved

water and sanitation, and household wealth/assets (Psaki et al., 2014; Vanz, Felix, Sica da Rocha, & Schwartz, 2015). Caregivers' gender is a categorical variable (male or female) and was determined in order to know whether there are gender-specific differences in the provision of care for CTB patients.

The purpose of this study was to examine the relationship between the reporting of CTB in Nigeria and variables pertinent to caregivers of young children. Its potential positive social change implications include, but are not limited to, providing the required evidence for public health stakeholders to work together towards improving caregivers' QOL through the provision of a social safety net. This would ultimately contribute to the prevention and control of CTB in the country, sub-region, continent, and world.

This chapter covers the background information on TB in both adults and children as well as the problem statement, which presents the actual gap in CTB literature and a logical argument and justification to address it. Other sections include the purpose of the study, the description of the study variables and an assumed relationship among them, the research questions and hypotheses which the study sought to answer, and the theoretical framework upon which it was grounded. The remaining sections include the description of the study design and methodology, the definition of terms, and the assumptions related to the study, as well as its scope, delimitations, limitations, and significance. Finally, the chapter ends with a description of the study's potential implications for social change as well as its summary.

Background

Although curable and preventable, TB is a highly infectious disease that kills worldwide (WHO, 2013a). It is caused by a bacterium known as *mycobacterium tuberculosis* and can affect any part of the body, although the lungs remain the organs mostly affected, giving rise to pulmonary TB. Extra-pulmonary TB is that which affects any organ other than the lungs. This study, however, focused on pulmonary TB in children aged 0-14 years. The infection is spread from person to person through the air as a result of coughing, sneezing, spitting, speaking or even singing by people with pulmonary TB (WHO, 2013a). A healthy person needs to inhale only a few of these bacteria to become infected. An infected person can transmit the bacteria to about 10 to 12 healthy individuals per year, although being infected with the bacteria is not synonymous with having the disease (CDC, 2012; WHO, 2013a).

CTB (or pediatric TB) refers to TB in children aged 0-14 years old (WHO, 2015a; CDC, 2014). According to the WHO (2016a), children accounted for 10% of the total global burden in 2015, which translates to an estimated 1 million CTB cases and 210,000 deaths. Once infected with *mycobacterium tuberculosis*, children tend to progress more quickly with the disease than adults (CDC, 2014). CTB was declared by the WHO in 2007 to be a neglected aspect of the TB epidemic, and as part of the ways of redressing this neglect, stakeholders under the leadership of the WHO proposed research priorities for this area. Six years later, the WHO (2013b) launched an initiative called the CTB roadmap, which outlines 10 key actions for addressing CTB at both the global and national levels. These actions are to:

1. Include the needs of children and adolescents in TB research
2. Collect and report better data on CTB
3. Develop training materials on CTB for health care personnel
4. Foster local expertise and leadership among child health personnel at all levels
5. Ensure that children are not left out of key interventions to control TB
6. Address social determinants of health in children through engagement, communication and collaboration with key stakeholders in health and other sectors
7. Develop integrated family and community-centered strategies for CTB
8. Address research gaps in all aspects of CTB prevention and control
9. Close all funding gaps for CTB at national and global levels
10. Form coalitions and partnerships and develop improved tools for CTB management

Again, research gaps featured prominently among these 10 key action points proposed in the roadmap. Heeding the world's call for increased research in CTB, scientists, policymakers, health care providers, and product developers have, over the years, conducted and published peer-reviewed research studies in virtually all the prioritized areas of CTB prevention and control (WHO, 2007; WHO, 2013a).

Several of these studies established the proportion of CTB cases out of the total TB disease population: 3.4% in India (Mukherjee et al., 2014), 7.9% in Peru (Chiang et al., 2015), 6% in Nigeria (WHO, 2015b) and the United States (Cruz & Martinez, 2015). Globally, Hamzaoui et al. (2014) highlighted that CTB accounted for 3.5 to 11% of the

caseload in high burden countries. However, Seddon and Shingadia (2014) assessed its global burden and found that its proportion ranged from less than 1% to 8% among the 22 high burden countries and from less than 1% to 3% in Western European and North American regions respectively.

Other studies looked at the relationship between CTB and risk factors such as socioeconomic factors, gender, household contacts with TB, and parent nationalities in Brazil (Stevens et al., 2014), Denmark (Søborg et al., 2011) and Norway (Krogh et al., 2010) but such studies are yet to be conducted in Nigeria. This is in spite of the fact that Nigeria is ranked fourth among the 22 high TB burdened countries after India, China, and Bangladesh, which collectively account for 80% of the global burden of the disease (WHO, 2013a). Moreover, the current WHO estimate of TB prevalence rate among both adults and children in Nigeria is 330 per 100,000, which translates to 590,000 people with all forms of TB (WHO, 2015b). This burden is further fueled in both adults and children by an ongoing HIV/AIDS epidemic and the emergence of drug resistant TB in the country. There were 3.4 million HIV/AIDS infected persons in Nigeria as at December 2012 (Joint United Nations Program on HIV/AIDS Nigeria, 2015), while the TB-HIV coinfection rate as of December 2014 was 18% (WHO, 2015b). Lastly, drug resistant TB (DR-TB) burden has been estimated to be 2.9% and 14% among new and retreatment TB cases respectively (WHO, 2015b). These rates have placed Nigeria among the 27 multi drug resistance TB high burden countries in the world (WHO, 2015b).

While it has been established that the HIV epidemic is a direct driver for TB outbreaks, Eldholm et al. (2016) found out that HIV coinfection is not a direct driver for the emergence and transmission of drug resistant TB. The TB-HIV coinfection and the menace of DR-TB have contributed to difficulties in the diagnosis and management of CTB, especially in developing countries (Getahun et al., 2010; Nieburg & Angelo, 2015; Poorana Ganga Devi & Swaminathan, 2013).

The presence of CTB in a community reflects recent and current transmission of the infection in that community, and the burden of the disease provides a clue to the level of TB prevention and control efforts being achieved in that particular setting (Hamzaoui et al., 2014). Additionally, the presence of infected children in a particular community is an indication of having a reservoir of the bacteria as well as the possibility of having future cases of infections if preventive measures are not taken (Swaminathan & Rekha, 2010). As stated by the WHO (2007), these preventive measures include addressing research gaps in CTB, hence the need for this research study, aimed at determining the relationship between caregivers' QOL, socioeconomic factors, gender, and reporting of CTB.

As noted earlier, similar studies with the same focus have been conducted in many countries, both developed and developing, but not in Nigeria. With the availability of tools to measure and quantify QOL (Brown et al., 2015; Payot & Barrington, 2011; Puspitasari, Rusmil, & Gurnida, 2013; WHO, 1994) this study is both desirable and feasible. The study findings may help to fill the identified gap in the literature and at the

same time provide policy makers and researchers with critical information that would help in the prevention and control of CTB in Nigeria.

Problem Statement

TB is a public health burden in Nigeria, estimated at 590,000 cases in 2014, ranked fourth among the 22 highest TB burdened countries in the World after India, China, and Bangladesh, in that order (WHO, 2015b). Furthermore, co-infection with HIV/AIDS, coupled with the emergence of drug resistant TB (Getahun et al., 2010; Nieburg & Angelo, 2015) underscores the need for further research in this area. To date, however, TB research has focused predominantly on adults, neglecting children 0-14 years old (Daniel et al., 2015; Erkens et al., 2014; Hamzaoui et al., 2014; Swaminathan & Rekha, 2010; WHO, 2013a). Additionally, TB prevalence surveys conducted under World Health Organization's (WHO) guidance in the 21 global focus countries, have excluded children aged 0-14 years (WHO, 2017).

Despite this neglect, an estimated 1 million CTB cases and 210,000 deaths occurred globally in 2015, accounting for 10% of the total burden (WHO, 2016a). In Nigeria, children accounted for only 6% of the 91,354 all forms of TB cases reported by the National TB Program (NTP) in 2014 (WHO, 2015b). This low proportion may have been due to neglect on the part of clinicians and public health practitioners to diagnose and treat TB in children. Thus, there is a need for all stakeholders in the NTP to be more proactive in not only detecting and treating more CTB cases in Nigeria, but in conducting more research work aimed at finding newer evidence based strategies for TB prevention and control in children.

In its research agenda for CTB (WHO, 2007) and CTB roadmap (WHO, 2013b), the role of caregivers/parents in the supervision of TB treatment in children has been emphasized. Further review of the literature has revealed that apart from supervising TB treatment, caregivers have several other important roles in uplifting the overall health and development of children. These include cognitive and socioemotional care (APA, 2016; Bornstein & Putnick, 2012; Meintjes & van Belkum, 2013; WHO, 2004a), growth monitoring, feeding practices and immunization (Nyavani, Gertrude, & Fhumudzani, 2016), diagnosis and treatment of both minor and major ailments, including TB (Belard et al., 2015; Thandar, Kyaw, Jimba, & Yasuoka, 2015).

For caregivers to discharge the above stated roles efficiently, they should be in their best physically, psychologically, socially, environmentally and economically (WHO, 2004a). These are measurable characteristics that could be of significance in determining whether a caregiver's child has an illness such as or not. Through systematic investigations, the relationship between these characteristics and reporting of TB in children may become clearer. The caregivers' quality of life (QOL) and socio-economic status (SES), which are both measurable, are concepts that encompasses all these characteristics. Furthermore, considering the cultural attributes of the study population that places the role of caregiving almost exclusively on women, it will desirable to add gender as a third variable in the study.

Caregivers' QOL includes issues like the way they feel about their natural life and health and whether they get the support they need from others or not. Furthermore, it entails the presence of physical pain or a medical illness, including how much they enjoy

life, to what extent they feel their life is meaningful, whether they have enough money to meet their needs, and whether they have an opportunity for leisure activities. Finally, caregivers' QOL takes account of how satisfied are they with themselves, their sleep, their friends, daily activities, capacity for work, sex life, place of living, and how often they have negative feelings such as despair or even depression (WHOQOL, 1994).

Caregivers' SES involves their educational status, income, occupation, access to improved water and sanitation and household wealth/assets (Psaki et al., 2014; Vanz et al., 2015) while their gender remains a categorical variable (male or female).

Several studies have found low QOL in adult TB patients as compared with healthy individuals in the same community (Brown et al., 2015; Dhuria, Sharma, & Ingle, 2008; de Farias et al., 2013; Mamani, Majzoobi, Ghahfarokhi, Esna-Ashari, & Keramat, 2014). However, there is a paucity of research studies examining the relationship between CTB and variables pertinent to caregivers of young children in Nigeria, in spite of the WHO's guidance that QOL and survival are ideal outcomes in the management of TB, especially in children (WHO, 2010). Moreover, strong cultural beliefs and diversity in Northern Nigeria, where the study took place, which restricts women caregivers to more of household duties and less of education and employment (Idris, Gwarzo, & Shehu, 2006) further justifies the need for this research.

Thus, this study measured QOL in caregivers of children with TB and compared it with those of caregivers of children without TB, using the standard WHOQOL-BREF questionnaire. This tool is an abbreviated 26-item version of the WHO's QOL assessment tool, the WHOQOL-100, containing items extracted from the WHOQOL-100

field trial data (WHO, 1994). The WHOQOL-BREF contains one item from each of the 24 facets of QOL included in the WHOQOL-100, plus two benchmark items from the general facet on overall QOL and general health survey, making it a 26-item tool. The facets were originally subsumed within one of six domains; however, factor analysis of the WHOQOL100 indicated that four domains namely physical, psychological, social relations and environment existed (WHO, 1994). The instrument measures an individual's overall perception of QOL and health. The four domain scores are scaled in a positive direction with higher scores indicating a higher QOL. Several studies have utilized the same approach to measure the QOL of caregivers/parents whose children are suffering from chronic diseases such as asthma, down syndrome, and Osteogenesis Imperfecta, among others (Oliveira & Limongi, 2011; Osman, Baxter-Jones, & Helms, 2001; Vanz et al., 2015).

The inclusion of gender as one of the independent variables stems from the fact that a number of research studies have advocated that the skill of caregiving differs among males and females. For instance, Sharma, Chakrabarti, and Grover (2016), through their review, established the existence of gender-specific differences in the provision of care in patients with dementia and other physical illnesses. Female caregivers tend to spend more time, carry out more personal-care tasks, and experience greater mental, physical and psychological strain than males. However, in nearly equal number of studies, they found no such differences, leading to the view that though there may be certain gender-specific differences in caregiving, these may not be clinically significant.

Purpose of the Study

The purpose of this observational cross-sectional study was to explore the relationship between the reporting of CTB and variables pertinent to caregivers of young children. The study may address the identified literature gap of paucity of information on QOL of caregivers of children affected by TB in Nigeria. The three independent variables (IV) are: caregivers' QOL, caregivers' SES, and caregivers' gender, while reporting of CTB is the dependent variable (DV).

Research Questions and Hypotheses

The following research questions and hypotheses informed this study:

RQ1: Is caregivers' QOL related to the reporting of CTB?

H₀₁: Caregivers' QOL is not related to the reporting of CTB.

H_{a1}: Caregivers' QOL is related to the reporting of CTB.

RQ2: Is caregivers' gender related to the reporting of CTB?

H₀₂: Caregivers' gender is not related to the reporting of CTB.

H_{a2}: Caregivers' gender is related to the reporting of CTB.

RQ3: Is caregivers' SES related to the reporting of CTB?

H₀₃: Caregivers' SES is not related to the reporting of CTB.

H_{a3}: Caregivers' SES is related to the reporting of CTB.

Theoretical Framework

The theoretical framework for this study was the Theory of Reasoned Action (TRA) /Theory of Planned Behavior (TPB). The TPB, formulated by Ajzen (1985), is a modified version of the TRA meant to accommodate perceived behavioral control

following the realization that behavior was not 100% voluntary and under control. Thus, it was expected to play critical role in helping public health researchers understand people's attitudes, intentions and behaviors towards public health issues, such as CTB (Glanz, Rimer & Viswnath, 2008). See Figure 1.

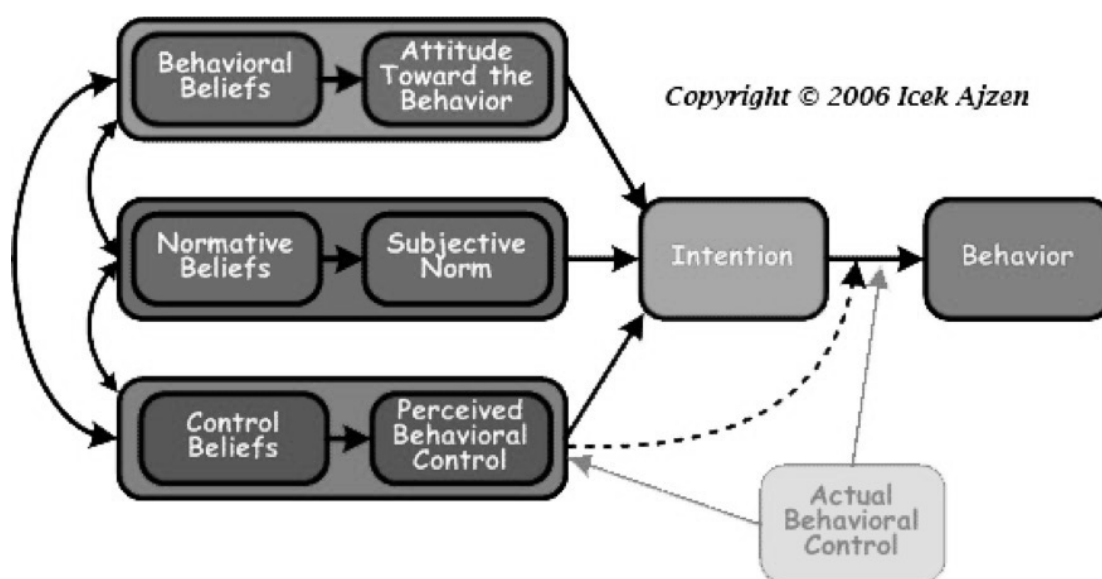


Figure 1. Theory of planned behavior. Retrieved from <http://people.umass.edu/aizen/tpb.diag.html>. Reproduced with permission.

Nature of the Study

The study method was quantitative using observational cross-sectional design, which was chosen because it was intended to survey a cross section of caregivers and determine the relationship between their QOL, SES, and gender with the reporting of TB in their children. Furthermore, the design was easy, convenient, and relatively cheap and enabled the conduct of face to face interviews with a sample of caregivers in Bauchi

State, Northeastern Nigeria within a period of 3 weeks. The results obtained were applicable to simpler populations from which the sample was drawn (Creswell, 2014).

The dependent variable was reporting of CTB, while the independent variables were caregivers' QOL, SES, and gender. CTB (or pediatric TB) refers to when children aged 0-14 years old are affected with TB (CDC, 2014; WHO, 2015a). The WHO (1994) defined QOL as "an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns", p. 11. SES of the respondents was measured by their highest educational level, since the WHOQOL-BREF questionnaire does not have other variables for measuring SES such income or occupation. Gender is a categorical variable and was measured at the nominal level (male or female).

The study was also informed by an internationally recognized tool, developed and used by the WHO, the WHOQOL-BREF survey. A limited number of participants were asked to sign a consent form before being interviewed. The questions helped determine information on the caregivers' QOL, SES, and gender, and excluded all personal identifiers such as names, street addresses, and telephone numbers, to ensure that the collected data remains confidential, in accordance with the general conduct of ethical biomedical studies as defined by the World Medical Association (WMA) declaration of Helsinki in 1964 and revised in 2013.

The QOL survey was administered over several weeks in Bauchi State, Northeastern Nigeria. The participants were caregivers whose children had been diagnosed with CTB from January 1, 2011 to December 31, 2015 as recorded in the State

Ministry of Health CTB database. Demographic characteristics of the respondents such as gender, age, and marital and educational status were analyzed. A multivariate logistic regression (MLR) model was used to determine relationships between the independent variables and the dependent variable. Adjusted odd ratios and related 95% confidence intervals were calculated using SPSS version 21.

Definitions

Caregiver: A person who takes care of a child suffering from TB in terms of looking after medications, consulting clinicians on behalf of the child, and addressing any other difficulties they may encounter while in care. A caregiver may or may not be paid for such services and could be the child's parent or guardian.

CTB: Also referred to as pediatric TB, CTB refers to when children aged 0-14 years old or less than 15 years of age are affected with TB (CDC, 2014; WHO, 2015a).

Contact Investigation for TB: This is carried out on all people, including children, who have close contact with infectious TB cases, with a view to detecting early active TB cases among them, thereby decreasing the disease severity and transmission to healthy individuals as well as identifying latent TB infection (LTBI) to allow preventive measures to be implemented (WHO, 2016).

Directly Observed Treatment, Short-course (DOTS): This is the name given to the TB control strategy recommended by the WHO whereby healthcare workers observe patients as they take in their medicines.

Drug Resistant TB: As opposed to drug-susceptible TB, a drug-resistant TB case is one in which there is a laboratory confirmation of resistance to one or more of the anti-TB drugs.

Epidemic: Refers to a situation where TB affects many persons at the same time, and spreads from one person to another in a community where the disease is not permanently prevalent.

Extra pulmonary TB: Refers to TB affecting organs of the body other than the lungs.

Gender: This is a categorical variable to be measured at a nominal level as either male or female.

High TB burden countries: Totaling 22, these are countries that account for approximately 80% of the total global estimated new cases of TB (WHO, 2015b).

HIV/AIDS: HIV stands for human immunodeficiency virus and those infected with it may develop to acquired immunodeficiency syndrome (AIDS) if untreated.

IGRA: Interferon-Gamma Release Assays (IGRA) are considered a modern alternative to Tuberculin Skin Test (TST) since it uses blood to detect the presence of *Mycobacterium tuberculosis* and is said to be not affected by previous vaccinations with BCG and requires only one patient visit (Yoshiyama, Harada, Higuchi, Saitou, & Kato, 2015).

Low income countries: These are countries with a Gross National Income (GNI) per capita of US \$1,026 or less (The World Bank, 2016).

Middle income countries: These are countries with a Gross National Income (GNI) per capita between US \$1,026 and US \$12,476 (The World Bank, 2016).

National TB Program (NTP): For this study, NTP stands for the National TB, Leprosy and Buruli Ulcer Control Program, established in 1988 under the Department of Public Health, Federal Ministry of Health, Abuja, Nigeria, with the mandate of controlling TB, leprosy, and ulcers in the country, in line with global targets.

Prevalence rate: This represents the burden of TB expressed as the number of people in a population who have TB at a given time.

Prevalence survey: This is a study to determine the prevalence of TB in a given population at a given point in time.

QOL: This is an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns (WHO, 1994).

SES: In this study, this was measured by the respondent's highest educational level, since the WHOQOL-BREF questionnaire does not have the other variables for measuring SES such as income, occupation, access to improved water and sanitation, and household wealth/assets

Stigma: This refers to a strong feeling of disapproval or discontent most people have towards TB.

Surveillance: This is the collection, analysis, and interpretation of TB data from a variety of sources in order to, among other reasons, evaluate the effectiveness of control

and preventive measures instituted by the NT) and support health planning and the allocation of appropriate resources within the health care system.

TB: For this study, TB refers to pulmonary TB, unless otherwise stated.

TST: Also known as tuberculin test or purified protein derivative (PPD) test, TST is used to determine if someone has developed an immune response to *Mycobacterium tuberculosis*.

Under-reporting: means the occurrence of TB being reported is less than what actually is the case.

WMA declaration of Helsinki: This refers to a declaration made by the World Medical Association (WMA) during its 18th General Assembly in Helsinki, Finland, June 1964, and amended during its 64th WMA General Assembly, Fortaleza, Brazil, October 2013. The declaration consists of sets of ethical principles guiding medical research involving human subjects, including research on identifiable human material and data. All physicians and those involved in medical research involving human subjects are encouraged to adopt these principles (WMA, 2016).

Assumptions

This study assumed that all the CTB cases reported between January 1, 2011 and December 31, 2015 in the Bauchi State Ministry of Health database were diagnosed based on NTP guidelines. Second, the study assumed that this database was accurate, comprehensive, and contains all the information required for the study. Third, the study assumed that caregivers of CTB cases gave reliable and valid information about their

QOL and SES during the interview. Last, it was assumed that the MLR model would establish a relationship between QOL, SES, gender, and CTB.

Scope and Delimitations

The delimitation in this study stems from the fact that it was limited in scope to Bauchi State and therefore used the state's CTB data instead of the national data. But for some important challenges such as high cost, inadequate logistics, and time constraints, the study's scope could have been widened to accommodate all 36 states and the Federal Capital Territory (FCT) Abuja.

Limitations

The limitations of this study are those inherent in cross-sectional designs. These are biases which if not controlled may result in an incorrect estimate of the relationship between the independent and the dependent variables. Selection bias was controlled through random sampling of study participants such that every eligible caregiver in the sampling frame stood equal chance of being selected in the sample, which would thus be representative of the entire study population, thereby ensuring external validity.

Second, as information was going to be obtained from the study subjects through face-to-face interviews, interviewer (recorder) bias could result when the interviewer interprets or records information differently among subjects or searches for information more diligently for one respondent as compared with another respondent. This is called differential misclassification, and was controlled by the use of an internationally recognized tool developed and used by the WHO, the WHOQOL-BREF questionnaire, consisting of close-ended questions with appropriate response options. The use of this

tool also ensured internal validity. Third, confounders are those minor variables whose presence may affect the variables being studied so that the results do not reflect the actual relationship between the variables under study (Pourhoseingholi, Baghestani, & Vahedi, 2012). These were controlled by matching, such that the study participants did not differ with respect to possible confounders such as age and gender.

Significance

Following the well-established neglect suffered by CTB research at the global, regional and country levels, this study became imperative, aimed at examining the relationship between reporting of CTB and variables pertinent to caregivers of young children in Nigeria. The study examined the relationship between QOL, SES and gender of caregivers and reporting of CTB in Nigeria. The study findings contributed additional knowledge on prevention and control of CTB in the country, as well as bridged the identified knowledge gap of paucity of information on QOL of caregivers of children affected by TB in Nigeria. Furthermore, the study clearly distinguished the important roles played by caregivers not only in TB prevention and control, but in public health care services in general.

The findings of this study may guide health care providers in their professional duties, which include, but are not limited to, targeting caregivers to ensure that they seek prompt medical attention for their children when the need arises. The findings of the study may provide evidence to policy makers on the need to empower caregivers socioeconomically as a panacea for addressing most health related challenges confronting children. Socioeconomic empowerment entails provision of basic social amenities such

as food, shelter, security, clean drinking water, education, employment opportunities, and basic health care services. In this way, the study may contribute to positive social change at family, community, and society levels.

Summary

Despite the fact that children form 10% of the global TB burden, they tend to be neglected in virtually all aspects of the disease continuum: research, prevention, care, and treatment. Some of the reasons given include difficulty in diagnosis, ignorance and stigma in the society, inadequate contact investigation, low access to laboratory tests, and insufficient trained health manpower. All these result in under-reporting of the cases in Nigeria where children constituted only 6% of the total TB cases reported in 2014. This challenge could be addressed by strengthening the surveillance system, studying the roles of NTPs in curbing the spread of CTB, and better identification of potential risk factors for the occurrence of CTB. The latter approach informed the study, hopefully with findings that may guide the NTP in Nigeria to establish innovative approaches not only to improve the reporting of CTB cases, but to adequately manage them so as to decrease associated morbidity and mortality.

Chapter 2 reviewed the existing literature on TB, with a special focus on CTB: what is known and what were the knowledge gaps and how the study filled such gaps. Chapter 3 explained the study design and methodology in detail, including the rationale for their choice, the descriptive analysis of the problems, and sources of data for the study and limitations and delimitations of the research methodology.

Chapter 2: Literature Review

Introduction

The purpose of this observational cross-sectional study was to explore the relationship between reporting of CTB in Nigeria and caregivers' quality of life (QOL), socio-economic status (SES) and gender. The study addressed the identified literature gap of paucity of information on QOL of caregivers of children affected by TB in Nigeria. This chapter discussed my literature search strategy, the theoretical framework chosen for the study, the literature review related to key variables and concepts, and a summary and conclusions section. The goal was to provide a thorough analysis of current peer-reviewed articles that relate to CTB, issues to do with its prevention such as immunization with Bacillus Calmette-Guérin (BCG) vaccine, diagnosis, treatment, and the performance of Nigeria's NTP.

The first section discussed the theoretical framework selected for the study, the TPB, its three constructs, and the external variables influencing it. The second section related the theoretical framework with the study. The third section focused on reviews of literature with respect to all the key variables and/or concepts studied: CTB, Nigeria's NTP, caregiver's QOL, SES, and gender. In the fourth section, I summarized the key issues reviewed in the chapter as well as provided inferences about CTB and caregivers. Finally, I concluded the chapter with a transition to the next chapter.

Literature Search Strategy

The literature search strategy for this study was to locate quantitative studies that examined relationships between CTB and variables pertinent to caregivers of young

children such as their QOL, SES, and gender. Thus, all quantitative studies on the subjects of interest, including retrospective studies and surveys, were explored, provided they were published in the English language. The key search terms used were *tuberculosis, childhood tuberculosis, pediatric tuberculosis, Nigeria, developing countries, theory of planned behavior, QOL, SES, gender, BCG, and TST*. Several databases, including Google Scholar, ProQuest, Medline, PUBMED, African Journal Online, and CINAHL, were used to perform the search.

Search engines such as Google were used to systematically search for peer-reviewed articles. Additional papers, abstracts, and publications related to this study were searched through the web sites of local and international organizations such as the Federal Ministry of Health (FMOH), Federal Office of Statistics, NTP, WHO, The World Bank, United Nations Children's Fund (UNICEF), United States Centers for Disease Control and Prevention (CDC), and Walden University Library. Moreover, the references from original research publications and reports were also appraised.

Finally, using a date parameter between January 1, 2010 and December 31, 2015, a total of 1,448 articles were obtained at the first instance. Out of these, 489 articles were duplicated and so were removed. Of the remaining 959 articles, 872 were excluded due to the fact that they were either conducted in developed countries, or were qualitative studies, or were not related to CTB risk factors. In the third step, the remaining 87 articles were found to be eligible for literature review. Figure 2 shows the summary of literature search strategy used in this study.

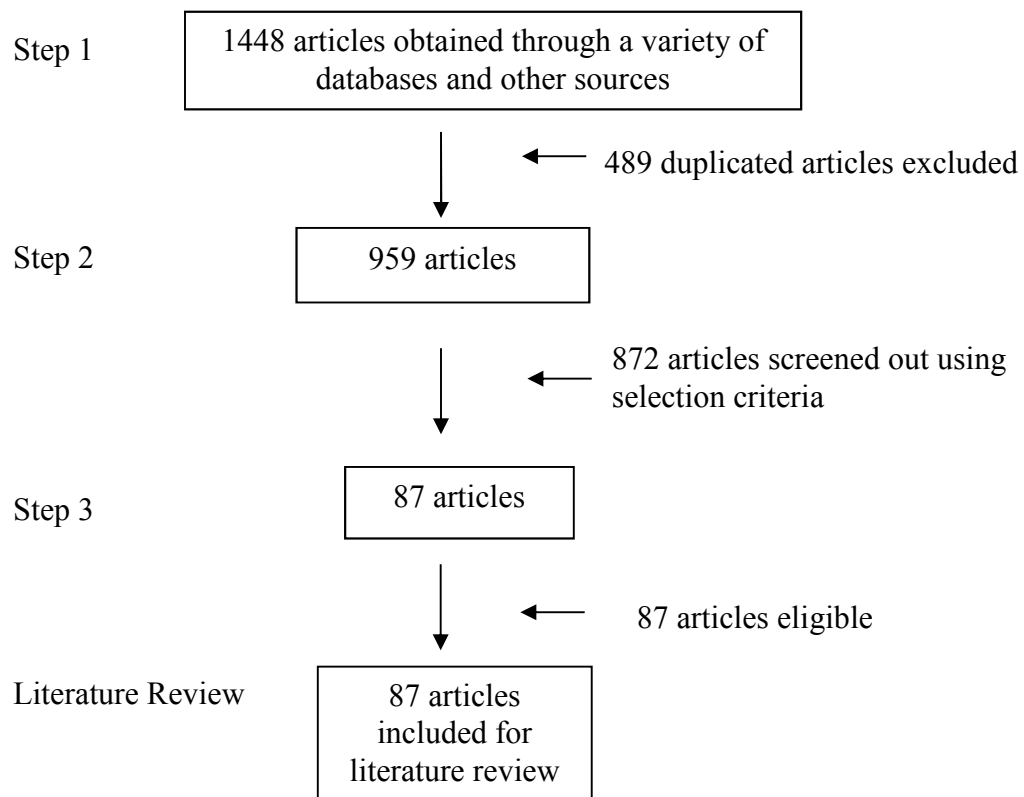


Figure 2. Literature search strategy of the study.

Theoretical Foundation

The Theory of Planned Behavior

This study used the TRA/TPB as its theoretical framework. The TPB is a modified form of the TRA which was formed in 1985 following the realization that the TRA was inherently weak in predicting deliberate or planned behavior since it (behavior) it was not 100% voluntary and under control (Ajzen, 1985). Thus, the TPB was meant to predict deliberate or planned behavior as well as psychological determinants of individuals (Ajzen & Fishbein, 1980), in addition to the other forms of behavior and attitude being predicted by TRA. Deliberate or planned behaviors are also known as volitional behaviors and they are those behaviors the individual has the greatest control over, carried out spontaneously, willingly, uncompelled, unforced, and voluntarily. The other forms of behavior are the autonomous and non-volitional behaviors especially exhibited by animals.

By predicting volitional behaviors, the TPB enabled me to relate caregivers QOL with CTB. As can be seen from figure 1, all the three constructs of the TPB could, for instance, lead to caregivers' intention and finally their behavior towards presenting their new born babies at health facilities for BCG vaccination and/or other health care services as the first step towards the prevention of CTB. The caregivers' level of commitment for this behavior may be influenced by their QOL: the higher their income level, which relates to higher QOL, the more committed they may be in carrying out such behaviors as established by Awusi, Anyanwu, and Okeleke (2009).

The strengths of this framework lie in its ability to help public health scholars to predict, explain and understand caregivers' attitudes, intentions and behaviors towards issues of public health importance, such as CTB. Secondly, the framework can provide the context upon which different health related intentions and behaviors, such as caregivers' role in supporting CTB care and treatment, can be explained (Glanz et al., 2008). However, these strengths are premised on the assumption that environmental or economic factors that may influence caregivers' intention to perform a health related behavior are taken care of by the framework. In reality, though, the theory does not account for these external variables, which include, but not limited to availability and access to resources, fear, threat, mood or past experience that are equally key in explaining the caregivers' attitudes, intentions and behaviors (LaMorte, 2016).

The Key Constructs of the TPB

For the TPB, the intention of an individual to carry out a particular behavior and the actual performance of that behavior are determined by three independent constructs: attitude towards the behavior, subjective norms to perform the behavior and perceived behavioral control (Glanz et al., 2008). These constructs are grounded on three belief structures viz: behavioral, normative, and perceived beliefs. The behavioral beliefs are those related to behavioral outcome and outcome evaluations; normative beliefs refer to the perceived expectations of others, and the satisfaction or dissatisfaction on the behavioral performance; and perceived beliefs are those related to the perceived factors that influence the easiness or difficulty of the performance of the behavior (Glanz et al., 2008).

Attitude

The behavioral intention (BI) of an individual is first determined by his/her attitude, which according to Ajzen (1985) is an individual's opinion about whether a behavior is positive or negative, depending on behavioral beliefs, and the perceived nature of the behavioral outcome. Individuals who believe that the outcome of their behavior would be positive tend to have a positive attitude towards performing that behavior. The opposite is the case for those with negative attitudes, who, according to Ajzen and Fishbein (1980) would declare the negative outcome that comes with that deed. Furthermore, the behavior of an individual tends to be influenced by and depend on several issues that are both personal and external to that individual.

Therefore, with TPB, an individual's attitude towards carrying out a particular behavior is determined by whether the outcome of that behavior is believed to be success or failure. Thus, attitude could be viewed as a product of behavioral beliefs as well as likely results of accomplishment or disappointment following behavioral performance. Simply put, where accomplishment is being expected, the beliefs and attitude towards performing a volitional behavior is likely to be positive. The opposite is the case when disappointment is being expected (Ajzen & Fishbein, 1980).

The attitude of parents and caregivers towards immunizing their children against vaccine preventable diseases, including TB, has generally been positive (Abidoye & Odeyemi, 2013; Chris-Otubor, Dangiwa, Ior, & Anukam, 2015; Nisar, Mirza, & Qadri, 2010). Furthermore, in a study in India, Jani, Bhambhani, and Thakor (2015) found out that 32.3% of caregivers interviewed knew that TB in children can be

prevented by BCG vaccine. This knowledge may have been as a result of both their orientation and enthusiasm towards the behavior on getting the BCG vaccine as protection for their newborn babies against TB. The possible outcomes if a child receives BCG vaccine could either be protection against TB (positive) or lack of it (negative) and this is known as attitude.

Subjective Norm

Next to attitude in determining an individual's BI is subjective norm, which is defined as "the perceived social pressure to perform or not to perform the behavior" in question (Ajzen, 1985, p. 188), or to engage or not to engage in a particular behavior. Furthermore, according to Glanz et al. (2008), subjective norm is seen as an individual's view of perception of getting an endorsement or lack of it in the performance of BI. It should be noted while the BI of an individual is determined by both his/her attitude and subjective norm, the latter is determined by the individual's normative influences, which is the individual's perception of social normative pressures that he or she should or should not perform such a behavior. Thus, this study could serve as a basis for health care professionals and researchers to tailor behaviorally based prevention programs (such as BCG vaccination and chemoprophylaxis with INH in the case of CTB) at the individual, family and community-based levels.

Perceived Behavioral Control

The concept of perceived behavioral control, introduced by Icek Ajzen in 1985, was added to the theory of reasoned action (TRA) in order to improve its predictive power. Thus, the TRA plus perceived behavioral control equals the theory of planned

behavior (TBP). Perceived behavioral control is a concept that examines one's self-efficacy or ability to perform a given behavior, given the belief that there are factors out there that facilitate or impede the successful performance of the behavior. Similar to Bandura's (1982) concept of self-efficacy, perceived behavioral control is the third determinant of BI after attitude and subjective norm, in that order, as shown in figure 1.

Furthermore, perceived behavioral control not only predicts BI but also can predict when people's perception of control properly equals their control over behavior thus revealing the individual's actual performance and control of the behavior. This view has been corroborated by Conn, Tripp-Reimer, and Maas (2003), who opined that perceived behavioral control could have a direct or indirect impact on BI. Likewise, Goh et al. (2016), in a cross-sectional study involving nursing home caregivers in Singapore, demonstrated a positive correlation between their perceived behavioral control (and attitude) and the provision of oral care to their inmates.

Yet, perceived behavioral control is itself influenced by variables (internal and external) which may hinder or promote conduct of the behavior and these include, but not limited to, perceptions of barriers, inhibitions, talents, resources, and opportunities (Ajzen, 1985; Ribera, D'Alessandro, & Grietens, 2007). As suggested by Ajzen (1985), availability and access to resources, coupled with the absence of obstacles against performing the behavior, is likely going to lead to a very high degree of perceived behavioral control.

Intention

Intention is a precursor of behavior, meaning that the intentions of individuals can predict their behavior. Apart from these two constructs, the TPB emphasizes strong relationships amongst all the constructs namely belief, attitude, subjective norm, perceived behavioral control and behavioral intention. This is in spite of the fact that each one of them is very distinct, yet relating closely with the next one and even precedes it. Yewhalaw et al. (2010) conducted a study in Ethiopia, Northeastern Africa, and the outcome revealed that 96% and 98% of the caregivers interviewed and living in at-risk villages perceived childhood malaria as preventable with insecticide treated nets (ITNs) and treatable in a health center with recommended anti-malarial medications respectively. This has clearly demonstrated the very high intention of these caregivers to prevent their children from getting malaria. The same expectation is hoped for with this study with respect to CTB.

External Variables Influencing the TPB

Demographic

Examples of demographic variables include education, occupation and income of caregivers. These are generally termed external variables (Conner & Norman, 2005), and are expected to have direct or indirect influence on the three constructs of the TPB and ultimately on intention and behavior of caregivers to for instance, take their children to the health center for BCG vaccination as well as to seek medical care for their children when the need arises. Caregivers' educational status is an important external variable that influences patronage of childhood health care services. Their background education

qualification, for instance, makes it easier for caregivers to comprehend the aims and objectives of childhood immunization program, its benefits, probable unpleasant effects and their remedies.

This may explain why cases of vaccine preventable diseases are more prevalent in the Northern than Southern Nigeria. The Northern region, known for its strong cultural beliefs and diversity, is comparatively less literate, poorer and less employed than its Southern counterpart (Idris, Gwarzo, & Shehu, 2006).

Furthermore, age of mothers and caregivers is an external variable that influences their knowledge and comprehension of childhood health care services. According to National Population Commission [NPC] (2014), the younger the mother is, the better would be her patronage of the available and accessible perinatal and postnatal health care services. This may have been due to the fact that younger women may be better educated and are able to access health education messages through both print and electronic media (Onasoga, Osaji, Alade, & Egbuniwe, 2014).

Finally, the income level of the caregiver which may reflect her educational and employment status, plays significant role on her attitude, subjective norm, perceived behavioral control and ultimately her intention to perform the behavior of taking her child for immunization and/or other health care services (UNICEF, 2009). As established by several studies, a strong relationship exists between family's income level and its behavioral intention towards childhood immunization services, including BCG (Awusi, Anyanwu, & Okeleke, 2009).

Another important external variable is the environmental influence on intention and behavior of caregivers in ensuring that their children enjoy TB preventive and control services. Access to qualitative health care services for children, for instance, could be very critical in shaping the behavioral intention of caregivers in ensuring that their children are protected and/or treated for TB. The nature of the physical environment is also very important in influencing the BI of the caregivers towards the health care needs of their children.

It has been established that the perception of caregivers in the developing world on the potential benefits of immunizing their children from vaccine preventable diseases differ from that of caregivers in the developed world (WHO, 2004b). The BI of educated and employed caregivers towards child development appears to be different from that of uneducated and unemployed caregivers (UNICEF, 2009).

Relating Theoretical Framework with the Study

The task of explaining human behavior and its complexities has not been an easy one for researchers and scientists. However, this was to change when Icek Ajzen proposed TPB in 1985. The use of the three determinants of TPB, attitude, subjective norm, and perceived behavioral control, have shown that human behavior is determined by the intention to perform the behavior (Glanz et al., 2008). Applying TPB to the predictive model of CTB, there are various determinants of preventive behavioral intention among caregivers towards CTB.

The beliefs of caregivers on the outcome of their children receiving BCG vaccination, and their health seeking behavior when children are sick, for instance, can all

be explained using the TPB. Furthermore, caregivers' attitude towards presenting their new born babies at health facilities for BCG vaccination and their beliefs in orthodox medical and health care services form their subjective norms towards receiving the vaccination as well as seeking prompt medical attention for their sick children. Likewise their perceived behavioral control over some high-risk behaviors, such as outright refusal to allow their children to receive BCG vaccination at birth or seeking help for their sick children from alternative providers of care rather than from orthodox medical and health care providers, can all be explained by the TPB. For instance, Conner and Norman (2005), in their research on predicting health behavior, observed that perceived behavioral control could influence or reduce *some* high-risk health behaviors of humans. This is because human behavior may sometimes be in the form of "incomplete volitional control". Thus, perceived behavioral control, and by extension TPB, needs to be linked to specific health issues such as in this case CTB (Ajzen, 1985).

The use of TPB in this study facilitated the understanding of researchers towards childhood illnesses: beginning from post-natal care through to promotion, prevention and management of childhood illnesses. According to WHO (2013c), post-natal care for the newborn include assessment of the baby during each post-natal care contact for signs of ill-health such as stopped feeding well, history of convulsions, fast breathing, fever, hypothermia; exclusive breast feeding until 6 months of age; cord care; and other postnatal care for the newborn such as delaying the bathing of newborn babies until 24 hours after birth, appropriate clothing for the baby, non-separation of mother and baby;

communicating and playing with the newborn, immunization with BCG and subsequently with other antigens as per the country's immunization schedule (WHO, 2013c).

The TPB as a theory employed in this study would assist in determining important behavioral, normative, and control beliefs that affect caregivers' behavioral intentions, which may lead to designing of interventions that would target caregivers in order to change their beliefs on child health: promotion, prevention, and management of childhood illnesses, including TB. The theory also helped in shaping their attitude, subjective norm and perceived behavioral control, there by positively changing their health seeking behaviors and intentions (Glanz et al., 2008).

Literature Review Related to Key Variables and/or Concepts

The following literature was reviewed for this study and includes specifically the key variables and concepts chosen.

Childhood Tuberculosis

Childhood tuberculosis, also called “pediatric TB” refers to when children aged 0-14 years old or less than 15 years of age are affected with TB (CDC, 2014; WHO, 2015a). The disease is most often caused when a child inhales *Mycobacterium tuberculosis* bacteria from an adult diagnosed with a bacteriologically confirmed pulmonary TB and often not on full and effective treatment. The child is thus infected and this results in the formation of a primary focus in the lung parenchyma, which may later spread, to regional lymph nodes and other organs of the body via the circulatory system. The infection may be contained at the affected local site or may be disseminated to other body organs, depending on the child's age, integrity of the immune system and

the virulence of the infecting microorganism. Children aged less than 2 years are more susceptible to having disseminated disease-affecting organs other than the lungs, which may result in the development of extra pulmonary disease (CDC, 2014).

The World Health Organization, in its 2016 global TB report, estimated that about 1.0 million CTB cases (representing 10% of the global estimated burden of 10.4 million TB cases) occurred in 2015, out of which an estimated 210,000 cases died. However, only 358, 521 CTB cases (representing 39% of the global estimated burden of 1.0 million CTB cases) were notified in 2014 by countries in the six WHO regions as shown in Table 1 (WHO, 2015b). In the same year in Nigeria, only 5481 CTB cases (representing 9.6% of the estimated 57 000 CTB cases) were notified (WHO, 2015b).

The wide gap between estimated and reported CTB cases may be due to difficulty faced by clinicians in diagnosing CTB cases since: they are seldom bacteriologically confirmed; clinicians who diagnose cases do not always report them to NTPs; high burdened TB countries are less likely to report them compared with adults; and methods of producing estimates differ, using either a dynamic model, statistical approaches or both (WHO, 2015a). Furthermore, children living with HIV/AIDS present another challenge when it comes to TB diagnosis because the HIV infection tend to complicate the interpretation of mantoux tests and chest x-rays, both of which are important tests in the diagnosis of CTB (Stop TB Partnership, 2015b).

Table 1

Estimated Number of Incident CTB Cases in 2014, Globally by WHO Region

WHO Region	Number of TB case		Estimated TB
	Notifications	Best Estimate	Incidence Uncertainty Level
AFR	90,523	330,000	290,000-370,000
AMR	10,489	27,000	25,000-29,000
EMR	42,028	80,000	64,000-97,000
EUR	9,898	31,000	28,000-34,000
SEAR	168,310	340,000	310,000-370,000
WPR	37,273	150,000	130,000-170,000
Global	358,521	1,000,000	900,000-1,100,000

Note. TB = tuberculosis; AFR = African; AMR = American; EMR = Eastern Mediterranean; EUR = European; SEAR = South East Asian Region; WPR = Western Pacific Region. Adapted from “Global TB Report,” by the World Health Organization, 2015, p. 33. Reproduced with permission.

The clinical features of CTB are more diverse and unspecific (WHO, 2007)

depending on the body organ affected. Thus, its diagnosis tends to be confirmed more on the basis of several criteria, namely typical clinical signs and symptoms of the disease, positive tuberculin skin test (TST) or positive TB blood test (IGRA), typical TB chest x-ray patterns, history of contact with an infectious TB case and bacteriological tests (CDC, 2014).

Typical clinical signs and symptoms include cough lasting two or more weeks, fever, and loss of weight and failure to gain weight. Positive TST (Mantoux) is when there is > 5 mm induration in high-risk children (severely malnourished or HIV infected) or > 10 mm in all other children.

Typical chest x-ray patterns include mediastinal adenopathy or a micronodular (miliary) appearance especially in HIV negative patients as well as presence of hilar shadows. Close contact with an infectious TB case entails “living in the same household or in frequent contact with as source case (e.g. caregiver) with sputum smear-positive TB” (WHO, 2007, p. 8).

The bacteriological tests include smear microscopy for acid-fast bacilli, molecular tests such as GeneXpert MTB/RIF assay, and culture of *M. tuberculosis*. The samples for these tests could be sputum, gastric or nasopharyngeal aspirate, blood and urine and the procedures for their collection include gastric aspiration, nasopharyngeal aspiration, venipuncture to collect blood and urine.

Having established the diagnosis of CTB, the next step would be to adequately and promptly treat it. Treating TB in children would require a focus on their mothers or caregivers (Stop TB Partnership, 2015a). This is especially true in mothers or caregivers that are living with HIV, since they are more likely to have TB given their compromised immune system that make them more vulnerable to opportunistic infections, including TB. Thus, these women or caregivers would require assistance and care from the health system so as to lessen the likelihood of transmitting the infections to their children. Furthermore, a successful treatment of drug susceptible CTB requires a dependable caregiver, correct dosage based on bodyweight and adjusted during treatment as shown in the Table 2.

However, this becomes a challenge in HIV co-infected and drug-resistant CTB as a result of drug interactions and difficulties with adherence to treatment, which are

further compounded by lack of stable pediatric syrup formulations for both anti-TB and antiretroviral drugs (Ugochukwu, 2010). The prevalence of HIV among children with TB was found to be very high, about 29.2%, in Lagos State, Southwestern Nigeria (Daniel et al., 2015). For these co-infected children, anti-retroviral drugs should be commenced within 2-8 weeks of starting and tolerating anti-TB treatment, while the treatment for multi-drug resistant TB in HIV-infected children follows the same pattern as for HIV uninfected children (Venturini et al., 2014).

Table 2

Childhood TB Drug Dosages

Drug	Dosage (mg/kg)	Range (mg/kg)	Maximum dose (mg/day)
Isoniazid (H)	10	7-15	300
Rifampicin (R)	15	10-20	600
Pyrazinamide (Z)	35	30-40	2000
Ethambutol (E)	20	15-25	1200

From *National Tuberculosis and Leprosy Control Program* (p. 7) by the Department of Public Health Nigeria. Copyright 2014 by the Department of Public Health Nigeria. Reproduced with permission.

For the treatment of drug susceptible CTB, B  lard et al. (2015) demonstrated that caregiver's practices and perceptions are critical to the successful drug delivery and outcome of the treatment. This is because in developing countries children drug formulations at required dosages are often unavailable, and more often than not tablets have to be split, crushed or dissolved all of which may lead to inaccurate dosing or outright refusal of medications due to bitter taste. Thus, WHO has recommended fixed dose combinations (FDCs) in order to address these challenges. Four, three or two

different anti-TB drugs are combined into a single tablet at fixed doses resulting in the formation of 4FDCs (RHZE); 3FDCs (RHZ); and 2FDCs (RH) respectively.

The WHO (2010) has recommended the use of RHZE for the initial period of two months followed by RH for four months in children living in settings with high HIV prevalence and/or high resistance to isoniazid, making six months as the total treatment duration. Furthermore, children with tuberculous and osteo-articular TB should receive RHZE for two months followed by 10 months of RH making a total of 12 months for the duration of treatment. However, CTB cases living in low HIV prevalence and isoniazid resistance settings could be treated with 3FDCs for two months followed by four months of 2FDCs.

From the foregoing, it can be stated that caregivers are very critical in the successful diagnosis and treatment of CTB. Furthermore, several researchers have established additional important roles caregivers play in uplifting the overall health and development of children. These include, but not limited to, cognitive and socioemotional care (APA, 2016; Bornstein & Putnick, 2012; Meintjes & van Belkum, 2013; WHO, 2004a), growth monitoring, feeding practices and immunization (Nyavani et al., 2016).), diagnosis and treatment of both minor and major ailments, including TB (Belard et al., 2015; Thandar et al., 2015).

However, their ability to discharge the above stated roles might be influenced by their macro-social and economic environment (Meintjes & van Belkum, 2013). These are vital societal structures that include its economic and political systems, social and cultural institutions, and demographic groupings. Caregivers, being part of the society,

would thus be affected by these socio-economic structures and their ensuing standards of living may impact on the roles they are expected to play in looking after children's health and welfare. Thus, it was relevant to determine the relationship between caregivers' QOL, SES, which were some of the macro-social variables, and the reporting of ailments, such as TB, in their children.

The inclusion of gender as one of the independent variables stemmed from the fact that a number of research studies have advocated that the skill of caregiving differs among males and females. For instance, Sharma, Chakrabarti and Grover (2016) established the existence of gender-specific differences in the provision of care for those with dementia or physical illnesses. Examples of these differences include time spent and duration of the caregiving, type of tasks, and reasons for caregiving. Thus, it was justifiable and desirable to determine if there were gender-specific differences in the provision of care for CTB cases.

The Nigeria National TB Program

Nigeria is a lower-middle-income country, having a Gross Domestic Product (GDP) of \$481.1 billion and an estimated population of 182.2 million people as at 2015, comprising of 51% females and 49% males, making it the most populous country in Africa (NPC, 2014; The World Bank, 2016). Moreover, children aged 0-14 years constitute 45.7% (80.7 million) of the entire population, while those aged 65 years and above constitute a mere 4%, signifying that Nigeria comprises of a young population with a broad-based population pyramid, as is typically found in developing countries with high fertility rates (NPC, 2014). The West African country is divided into 36 states plus

Abuja, the nation's capital city, 774 local government areas (LGAs), all grouped into six geopolitical zones: North Central, North East, North West, South East, South-South, and South West. Furthermore, it occupies an estimated 923, 768 square kilometers of land mass, extending from the Gulf of Guinea in the south to the borders of the Sahara Desert in the North corresponding to latitudes 4°16' and 13°53' north and longitudes 2°40' and 14°41' east. The country is geographically diverse, consisting of both low and highlands as well as wet and dry seasons (NPC, 2014).

In order to achieve quality health for all Nigerians, a national health policy was articulated in 1988 and revised in 2004. The policy, which spelt out the goals, structure, strategy, and policy direction of the country's health care delivery system as well as the roles and responsibilities of different tiers of government and non-governmental organizations, has the overall aim of providing unhindered access to primary, secondary and tertiary health care services for all Nigerians in the spirit of social justice, equity, and the ideals of freedom and opportunity as enshrined in the 1999 Constitution of the Federal Republic of Nigeria. The key targets of the policy include the reduction of under-5 and maternal mortality rates, as well as reduction in the burden of HIV/AIDS, TB and Malaria by the year 2015 (NPC, 2014).

In order to reduce the burden of TB in the country, the National TB and Leprosy Control Program (NTBLCP), herein referred to as the National TB Program (NTP), was established in 1988. The NTP, which is a unit in the department of Public Health, Federal Ministry of Health, Abuja, has been saddled with the responsibility of controlling TB, Buruli ulcer and Leprosy in Nigeria with the overall goal of reducing significantly the

burden of these three diseases in line with the global targets. Structured along the three tiers of government, namely, federal, state and local government levels, the federal level is responsible for policy development, tertiary care, mobilization and development of human and material resource and provision of technical support to state programs.

The state programs coordinate TB control activities, provide secondary care as well as technical management to program implementation at the Local Government Area (LGA) level. The LGA is the operational level (basic management unit) of the NTP. The human resource needs as well as the training of various cadres of health care workers to implement TB control activities is provided by the National TB and Leprosy Training Centre (NTBLTC) in Zaria, Northwestern Nigeria. This institution also houses a referral hospital with a 140-bed capacity as well as the National TB Reference Laboratory (FMOH, 2014).

With active support from development partners and other stakeholders, the NTP has, over the years, established a total of 5,863 TB service points and 1, 881 microscopy centers distributed across the 774 LGAs in the country, all of them integrated into the existing health system infrastructure and general health care services (FMOH, 2014). These services are implemented in collaboration with the HIV/AIDS control program at various levels of the health care system, the private health care providers, and the community and development partners. Part of these services the NTP renders includes the diagnosis and classification of TB in children as illustrated in Figure 3.

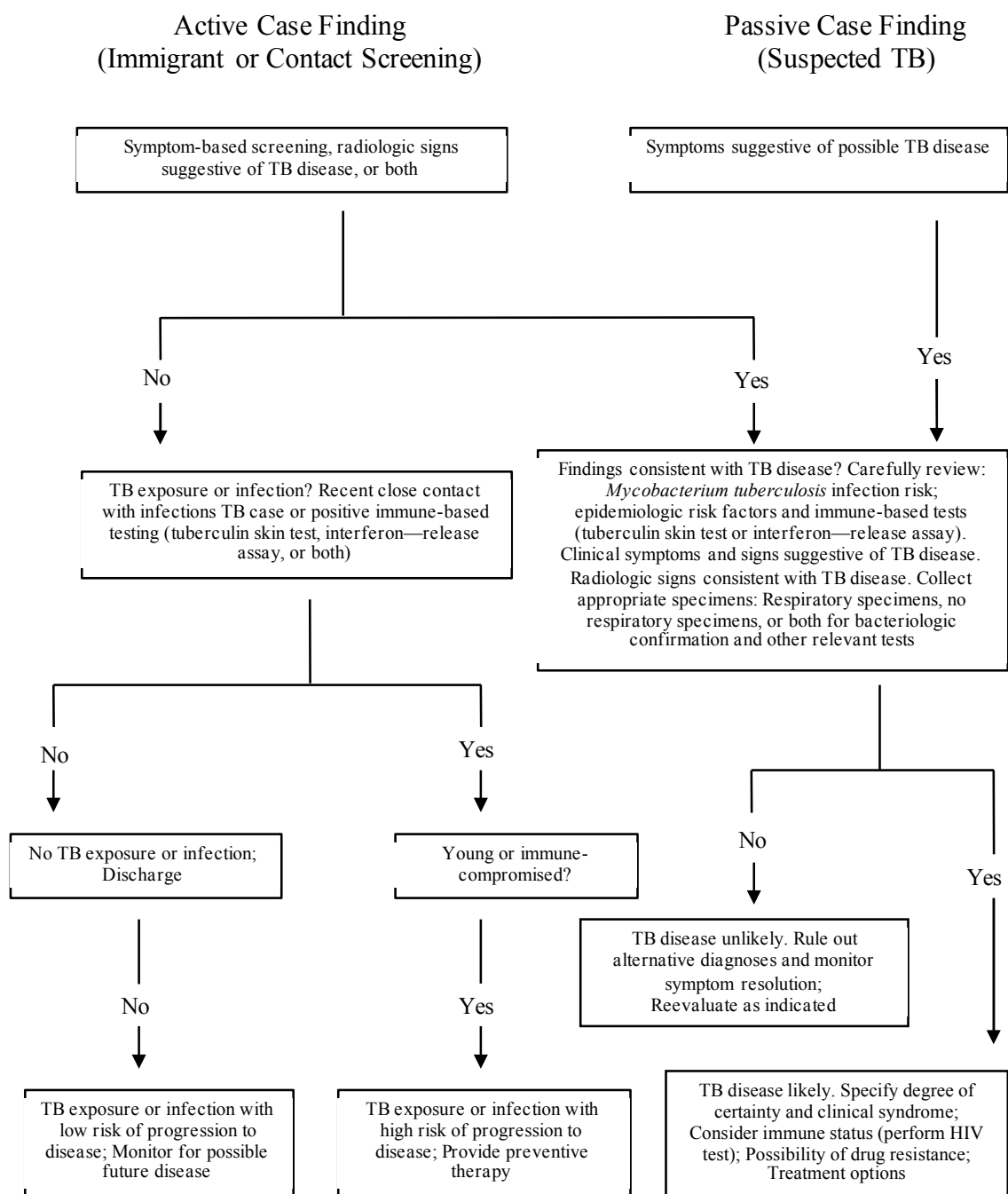


Figure 3. Algorithm for the diagnosis and classification of tuberculosis (TB) in children. Adapted from Perez-Velez, C. M., & Marais, B. J. (2012). Tuberculosis in children. *New England Journal of Medicine*, 367, 348-61. doi:10.1056/NEJMra1008049. Reproduced with permission.

However, looking at the trend of CTB notifications from 2008 to 2014, as depicted in Table 3, one could clearly deduce that although there has been an increase in the number of case notifications over the period, the WHO recommended target of at least 10% CTB cases out of all forms has never really been achieved.

Table 3

Trend of Childhood TB Cases Notified in Nigeria from 2008 to 2014

Year	All Forms of TB	All Forms of CTB	Percentage of CTB Among All Forms
2008	90,311	1,324	1.5
2009	239,110	3,030	1.3
2010	180,894	5,794	3.2
2011	93,050	5,836	6.3
2012	97,853	5,687	5.8
2013	100,401	5,776	6.0
2014	91,354	5,481	6.0

From *National Tuberculosis and Leprosy Control Program* (p. 7) by the Department of Public Health Nigeria. Copyright 2014 by the Department of Public Health Nigeria. Reproduced with permission.

With respect to the treatment of children diagnosed with drug susceptible TB, the NTP has adopted two standardized treatment regimens:

1. Standard six-month treatment regimen for all children with all forms of TB (newly diagnosed or previously treated PTB and EPTB) except TB meningitis and osteo-articular TB. This is known as regimen one for children: 2(RHZ+E)/4(RH) as shown in Table 4.

Table 4

Regimen and Dosages for Children with Susceptible PTB/EPTB Cases

Daily Regimen	Weight			
	<5 kg	5-9 kg	>9-13 kg	>13-18 kg
Intensive phase (2 months)				
<i>Combined tablets of RHZ (60 mg +30 mg+150 mg)</i>	1	2	3	4
<i>Ethambutol tablet (100 mg)</i>	1	2	3	4
Continuation phase (4 months)				
<i>Combined tablets of RH (60 mg +60 mg)</i>	1	2	3	4

Note. PTB = Pulmonary TB; EPTB = Extra-pulmonary TB; RHZ = Rifampicin, Isoniazid, Pyrazinamide; RH = Rifampicin, Isoniazid. From *National Tuberculosis and Leprosy Control Program* (p. 7) by the Department of Public Health Nigeria. Copyright 2014 by the Department of Public Health Nigeria. Reproduced with permission.

2. Standard 12 months treatment regimen for all CTB cases with TB meningitis and osteo-articular TB. This is known as regimen two for children:
2(RHZ+E)/10(RH) as shown in Table 5.

Table 5

Regimen and Dosages for Children with TB Meningitis and Osteo-articular TB

Daily Regimen	Weight			
	<5 kg	5-9 kg	>9-13 kg	>13-18 kg
Intensive phase (2 months)				
Combined tablets of RHZ (60 mg +30 mg+150 mg)	1	2	3	4
Ethambutol tablet (10 0mg)	1	2	3	4
Continuation phase (10 months)				
Combined tablets of RH (60 mg +60 mg)	1	2	3	4

Note. RHZ = Rifampicin, Isoniazid, Pyrazinamide; RH = Rifampicin, Isoniazid. From *National Tuberculosis and Leprosy Control Program* (p. 7) by the Department of Public Health Nigeria. Copyright 2014 by the Department of Public Health Nigeria. Reproduced with permission.

Preventive Measures

To safeguard against having to go through the rigors of establishing the diagnosis and managing a case of CTB, preventive measures need to be observed. These include, but not limited to, vaccination of children at birth with BCG, contact investigation and provision of chemoprophylaxis to TB free children, and ensuring that all bacteriologically confirmed pulmonary TB cases (infectious) are identified and treated successfully in line with the NTP/WHO recommended strategies (Directly Observed Treatment, Short-course or DOTS strategy, Stop TB strategy and End TB strategy) in order to break the cycle of transmission to healthy individuals in the community, while at the same time instituting infection control measures in health care facilities.

Despite these preventive measures, children with TB continue to be missed by clinicians. According to Lobato, Mohle-Boetani, and Royce (2000), failure to detect and adequately manage adult source cases and failure to screen and effectively treat children exposed to TB are “important missed opportunities” to prevent CTB.

BCG Vaccination

Produced by Camille Guérin and Albert Calmette at the Pasteur Institute, Paris in 1921, the *Bacillus Calmette-Guérin* (BCG) vaccine is an attenuated form of *Mycobacterium bovis*, a bacteria closely linked to *Mycobacterium tuberculosis*, the bacteria responsible for TB (CDC, 2011). The WHO Expert Committee on Biological Standardization first approved it at its eighteenth meeting held in Geneva in 1966 to member countries as a vaccine for effective immunization against TB. Since then, many high TB burdened countries, such as Nigeria has included it among their National Childhood Immunization Programs and given to infants at birth. Moreover, the vaccine has very few side effects. Apart from the scar it produces at the injection site and the rare anaphylactic reaction that occur in less than one in a million doses, the vaccine does not have serious side effects that could influence parents’ compliance (WHO, 2016b).

However, disagreements among scientists about its effectiveness have been published in the literature (Abubakar et al., 2014; CDC, 1996; Colditz et al., 1994). For instance, there is evidence that it does not prevent children from primary infection nor does it prevent reactivation of latent pulmonary infection, which has been adjudged to be the main source of bacterial spread in the community. Its impact on the transmission of *mycobacterium tuberculosis* in the community is therefore limited. Fortunately, many

parents/caregivers, especially in high TB burdened countries are not aware of this rather academic discourse over BCG, as such their attitudes towards its utilization has remained positive (WHO, 2016b).

Notwithstanding these academic debates about its effectiveness, there is a consensus that BCG offers about 60-80% protection against tuberculous meningitis and disseminated TB in children (Abubakar et al., 2014; Perez-Velez & Marais, 2012) as well as significantly reduces the risk of TB by 50% (WHO, 2016b; Colditz et al., 1994). Thus, it should somehow be useful, especially in developing countries such as Nigeria, where TB is endemic, with prevalent cases of TB meningitis and disseminated TB among children (WHO, 2016b). Moreover, the vaccine's low efficacy in preventing TB infection and on the overall transmission of the TB bacillus in the general population, its perceived benefit of conferring direct individual protective effect especially among the youngest recipients, has probably motivated caregivers and parents to get their children vaccinated at birth or at the first contact with the health service. However, booster doses are not recommended, as there is no known advantage of doing so.

Other unique advantages of the vaccine, which have probably led to increased patronage by caregivers and parents include the fact that the vaccine can be given at birth or any time thereafter; requires just a single inoculation to produce a long-lasting immune response, typified with a scar which is useful for epidemiological surveillance; it is safe; it is relatively stable as freeze-dried vaccine; it is cheap (from 0.02 to 0.5 U.S. dollars).

It was not surprising, therefore that, in 1992, approximately 100 million newborns and children received the vaccine worldwide, resulting in global immunization coverage

of 85% (Lagrange et al., 1998). Several countries, especially developing, have adopted the WHO recommendations on “optimal utilization of BCG” despite its shortcomings except in persons exposed to TB or at risk of progressing from TB infection to disease, such as those who are immunocompromised as a result of HIV/AIDS (WHO, 2004b).

Treatment with WHO recommended TB Control Strategies

The above-mentioned limitations of BCG has brought to the fore the need for an effective TB control strategy that would ensure early detection and effective treatment of pulmonary (infectious) TB cases in the community in order to curtail the transmission of the microorganism from infected to healthy individuals, including children. Following the declaration of TB as a “global emergency” in 1993, the WHO has, over the years, recommended various TB control strategies to member countries for implementation.

Beginning with the Directly Observed Treatment, Short-course (DOTS) strategy in 1994, to the Stop TB strategy in 2006, to the current End TB strategy in 2015, the WHO has dubbed them as highly efficient and cost-effective strategies of curing TB, especially in high burdened countries. The DOTS strategy, with five components, was launched in 1994 with the aim of detecting 70% of infectious TB cases and curing 85% of them. In 2006, a revision was made to the DOTS strategy to pave way for Stop TB strategy, with six components and the goal of dramatically reducing the global burden of TB by 2015 in line with the Millennium Development Goals (MDGs) and the Stop TB Partnership targets.

The current End TB strategy, endorsed by the 67th World Health Assembly in 2014, and launched in 2015, is designed in anticipation of the post MDGs era and is

aimed at ending the global TB epidemic, with targets to reduce TB deaths by 95% and to cut new cases by 90% between 2015 and 2035, and to ensure that no family is burdened with catastrophic expenses due to TB (WHO, 2016c). Furthermore, the End TB strategy speaks to the health-related target under the United Nations Sustainable Development Goal (SDG) 3 that calls for ending the TB epidemic (United Nations [UN], 2015).

Contact Investigation

In line with the End TB Strategy, all people who have close contact with infectious TB case(s) should be investigated because they are at high risk of infection and disease particularly those less than five years of age and within the first year of contact (Fox, Barry, Britton, & Marks, 2013; WHO, 2016c). This intervention, known as TB contact investigation, has been found to contribute immensely to early identification of active TB, reducing its severity and curtailing its spread to other individuals in the community.

Contact investigation also helps in the identification of latent TB infection (LTBI), paving way for the institution of preventive measures: treatment with isoniazid for at least 6 months (Rutherford et al., 2012). The intervention has also proved to be very useful for detecting TB in children, including those exposed to an index case of drug-resistant TB and people living with HIV (PLWHIV). Equally exposed to *Mycobacterium tuberculosis* are health care workers (HCWs) working in health care facilities especially in resource-limited-settings. The risk of nosocomial transmission of *Mycobacterium tuberculosis* among HCWs, medical and nursing students has been documented (WHO, 1999).

TB Infection Control

Infection Control (IC) measures should therefore be instituted to safeguard the health and prevent the occurrence of such nosocomial transmission. The measures include administrative, environmental and personal respiratory protection.

Administrative infection control measures are aimed at preventing *M. tuberculosis* droplet nuclei from being generated in the first place through the development and implementation of IC plan that spells out the measures to be taken in a given health facility to achieve this goal. Examples of such measures are the prompt separation and isolation of infectious TB patients and the prompt initiation of appropriate anti-TB treatment.

Second, as the name implies, environmental IC measures are aimed at reducing the concentration of drop nuclei in the surrounding air through, for instance, the opening of windows and doors in a consulting or ward in order to create natural cross ventilation and the use of a standing fan in a consulting room or ward so as to control the direction of air flow.

Lastly, personal respiratory protection is aimed at preventing HCWs from inhaling infectious droplet materials flying in the air through the use of personal protective equipment such as the N95 face mask to cover the mouth and nose and sieve out infectious TB droplet nuclei (WHO, 1999).

The Role of Caregivers in the Prevention and Control of Childhood TB

The role of caregivers in safeguarding the overall health and development of children, including their cognitive and socioemotional care has been universally

acknowledged (APA, 2016; Bornstein & Putnick, 2012; Meintjes & van Belkum, 2013; WHO, 2004a). Generally speaking, the word caregiver has been used by researchers to denote child's parent (father or mother), grandparent, childcare provider, early childhood teacher, and/or significant family members. This study adopted this broad definition so that any available person that fits the continuum was recruited as a participant, in accordance with the general conduct of ethical biomedical studies as defined by the WMA Declaration of Helsinki, 1964, and revised lately in 2013.

It is important to point out that caregiving is traditionally linked with parenting (Talley & Montgomery, 2013), and in nearly all cultures, women, particularly mothers, are known to care for young children by being directly responsible for meeting their physical and emotional needs (Talley & Montgomery, 2013). It is also necessary to point out that due to economic difficulties faced by families especially in resource-limited settings, new set of caregivers different from mothers are emerging because more mothers are returning to full employment shortly after putting to bed (Talley & Montgomery, 2013).

In any case, caregivers have important roles to play in safeguarding the health of their children through the institution of the afore-mentioned preventive measures against TB. To do this efficiently, they need to possess the right knowledge on TB as a disease and the protection that BCG confers on children against the disease. Right knowledge on TB entails that a caregiver knows the case definition of TB, its cause, how it is transmitted, and the fact that it is a completely curable disease provided the right medications are taken in the right doses within the right duration.

Secondly, the caregiver should know the benefits of the BCG vaccine and INH chemoprophylaxis for the prevention of the disease. Thus, possessing the right knowledge on the part of the caregiver would have had a positive impact on him/her to do what is right for her children's health care needs. However, many caregivers and parents lack this right knowledge, and as demonstrated by Belard et al. (2015), this may lead to children on treatment and care being given drugs at sub-therapeutic levels, thus posing significant challenges to the prevention and control of CTB. This is more pronounced in developing countries, where CTB is believed to be caused by supernatural factors such as a curse by the gods or evil spirits and therefore amenable to complementary and alternative medicine (CAM) rather than by allopathic means (Mustafa, Bashir, & Aslam, 2016). Sick children would rather be presented to CAM for "cure" rather than to a trained health care worker who would presume and investigate for TB and commence prompt treatment, leading to missed opportunities to diagnose, adequately treat the disease there by preventing TB among children.

In such circumstances, such children are only taken to health centers after a long delay, resulting in late diagnosis, poor prognosis, and poor treatment outcomes including disabilities and deaths (Lobato et al., 2000). In a cross sectional observational, descriptive epidemiological study in rural India, Jani et al. (2015) found that only 32.3% of caregivers knew that TB can be prevented by BCG vaccine; 45.0 % caregivers of patients had knowledge regarding mode of spread of TB infection to others; 58.9% knew about the curability of the disease; and 68.9% had knowledge regarding DOTS (Directly Observed Treatment Short course chemotherapy) center for TB treatment.

Measuring Caregivers' QOL

For caregivers to deliver on family and societal mandates, they need to be in their best physically, psychologically, socially and environmentally. Thus, this study intends to measure these four QOL domains and their overall perception of QOL and health and compare them with those of caregivers whose children do not have TB using the WHOQOL-BREF questionnaire. The four domain scores are scaled in a positive direction from 1 to 5, with higher score indicating a higher QOL, except for 2 items in domain 1 and 1 item in domain 2 that have to be reversed before scoring. Summed and transformed scores of the overall QOL and the four QOL domains were created as per the scoring instructions provided on the WHO-QOL BREF questionnaire. Thus, it was very interesting and desirable to know whether caregivers whose children have TB had lower QOL than those whose children did not have TB. This may establish a possible evidence to back public health authorities in uplifting the QOL of caregivers whose children have TB, thereby contributing to the prevention and control of TB not only among their children, but in the society at large.

Several studies have utilized the same approach and measured the QOL of caregivers/parents whose children are suffering from chronic diseases such as Asthma, Down syndrome and Osteogenesis Imperfecta, just to mention a few (Osman et al., 2001; Oliveira & Limongi, 2011; Vanz et al., 2015) and compared them with the QOL of caregivers from the general population. Apart from the caregivers' QOL, the other two independent variables this study intends to measure are the caregivers' gender and socio-economic status.

Measuring Caregivers' Gender

The inclusion of caregivers' gender as one of the independent variables stems from the fact that a number of research studies have advocated that the skill of caregiving differs among males and females. For instance, Sharma, Chakrabarti and Grover (2016) established the existence of gender-specific differences in the provision of care for those with dementia or physical illnesses. Examples of these differences include time spent and duration of the caregiving, type of tasks, and reasons for caregiving. Thus, it was justifiable and desirable to determine if there were gender-specific differences in the provision of care for CTB cases.

Measuring Caregivers' Socio-Economic-Status

In this study, SES of parents/caregivers was determined by their educational level, since this was the only SES-related variable that was contained in the WHOQOL-BREF questionnaire. SES is one of the three independent variables this study seeks to explore with respect to its relationship with the reporting of CTB in Nigeria.

Without any prejudice to the findings of the study, this relationship has been explored elsewhere. Jani et al. (2015) found out that educational level or literacy status of caregivers had significant influence on their awareness about TB. This awareness would translate into having a big impact on their health seeking behavior. Those with low educational status, especially in developing countries, tend to have less utilization of the available health care services as compared with those having high educational status. In case of the former, transportation costs to the nearest health center may be an issue since they may be unemployed and lack any source of income.

Other barriers preventing access to health care services include long distance to the health centers, use fees, presence of armed conflicts, and unsatisfactory services at the health center due to probably insufficient trained manpower, attitude of health care workers, stock out of vaccines and essential medicines at the health center. Putting these barriers within the context of Nigeria, studies have established disparities in educational status of women between the Northern and Southern regions (NPC, 2014). The latter has a higher percentage of educated women than the former.

For instance, the NPC (2014) established illiteracy in 70% of women and 35% of men in the Northeast and Northwest regions as compared with 15% of women and 8% of men in the entire Southern Nigeria. This disparity may be one of the reasons for the caregivers' lack of knowledge on CTB and on the benefits of BCG vaccination and INH chemoprophylaxis for its prevention. This may place the Northern region at a disadvantaged position when it comes to the role of caregivers in the prevention and control of CTB in Nigeria.

Summary and Conclusions

CTB remains a neglected aspect of the TB epidemic (WHO, 2007) despite accounting for 10% of the global TB burden and responsible for 210,000 deaths in 2015 (WHO, 2016a). The need for more research studies in CTB especially in low-income countries was one of the several action points proposed by stakeholders to redress this neglect (Nelson & Wells, 2004; WHO, 2007; WHO, 2013b). Such studies have been conducted in several low-middle income countries (Krogh et al., 2010; Søborg et al., 2011; Stevens et al., 2014).

However, there is paucity of research studies examining the relationship between the reporting of CTB and variables pertinent to caregivers of young children in Nigeria, hence the need for this research whose purpose was to determine the relationship between caregivers' QOL, socioeconomic factors, gender, and reporting of CTB. With the availability of tools to measure and quantify QOL (Brown et al., 2015; Payot & Barrington, 2011; Puspitasari et al., 2013; WHO, 1994) this study is not only desirable, but feasible.

Chapter 3 presented the description of the study's research design and rationale, methodology, threats to validity, ethical procedures, and a summary.

Chapter 3: Research Method

Introduction

The purpose of this study was to examine the relationship between reporting of CTB in Nigeria and caregivers' QOL, SES and gender. This chapter offers an in-depth explanation of the study's research design and rationale, methodology, threats to internal and external validity and finally a summary of all what was discussed. The research design includes the study's variables, design, and research questions, while the methodology includes the study's population, sample size, sampling procedures, data collection procedures, and instrumentation. Threats to study's validity includes both internal and external, while ethical procedures include the institutional review board (IRB) application, approval and ethical issues concerning confidentiality.

Research Design and Rationale

The study was a cross-sectional survey of caregivers whose children had been diagnosed with CTB in Bauchi State, Northeastern Nigeria from January 1, 2011 to December 31, 2015 as recorded in the State Ministry of Health CTB database. The purpose of the study was to determine the relationship between caregivers' QOL, SES, gender, and the reporting of TB in their children. The design was chosen because it is easy, convenient, and inexpensive (Szklo & Nieto, 2014), and enabled face to face interviews with a sample of the caregivers so as to determine their QOL, SES, and gender in particular locations and at a given point in time. Possible associations were determined between these independent variables and the disease outcome. The results obtained were applied to simpler populations from which the study sample was drawn.

The independent variables were the QOL, SES, and gender of the caregivers, while the dependent variable or outcome was reporting of CTB. The independent variables were measured through face-to-face interviews with a sample of caregivers, using an internationally recognized tool developed and used by the WHO, the WHOQOL-BREF questionnaire. All respondents had signed consent forms before being interviewed. The questions ascertained information on the caregivers' QOL, SES, and gender and excluded all personal identifiers such as names, street addresses, and telephone numbers so as to ensure that the collected data remains confidential, in accordance with the general conduct of ethical biomedical studies as defined by the WMA Declaration of Helsinki in 1964 and revised in 2013.

Information on the dependent variable was extracted and reviewed retrospectively by the researcher, from the Bauchi State CTB database for the period January 1, 2011 to December 31, 2015, taking care to avoid double reporting. Figure 4 illustrates the association between the four concepts being studied in this research while Table 1 describes their definitions and categorization.

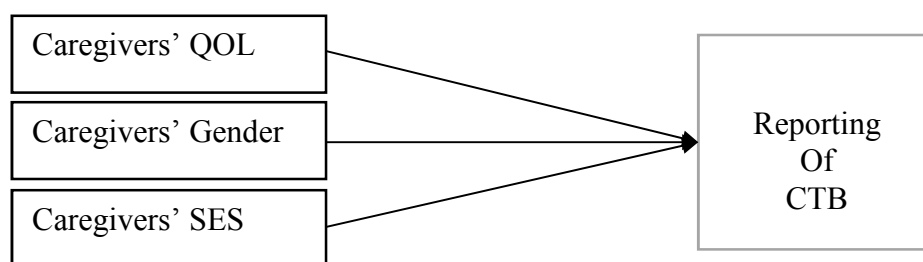


Figure 4. Theorized relationship between the study concepts.

Table 6

Definition and Categorization of Variables Used in the Study

Variable	Description	Category
<i>Dependent variable</i>		
CTB	When children under 14 are diagnosed with TB (also referred to as “pediatric TB”)	0=No TB 1=TB present
<i>Independent variables</i>		
QOL	The WHOQOL-BREF questionnaire was used to measure the QOL of each respondent. The tool consists of four domain scores (TPHSSRC, TPsychSSRC, TSRSS, TEnviroSS) and two individually scored items about a respondent’s overall perception of QOL and health.	The four domain scores are scaled in a positive direction with higher score indicating a higher QOL, except for 2 items in domain 1 and 1 item in domain 2 that must be reversed before scoring. OQOL (1-5) TPHSSRC (1-5) TPsychSSRC (1-5) TSRSS (1-5) TEnviroSS (1-5) Summed and transformed scores of overall QOL and four QOL domains were created as per scoring instructions provided on WHO-QOL BREF questionnaire
Socio-economic status	Respondent’s highest educational level	Educational level: 0= not at all 1= elementary school 2= high school 3= college;
Gender	Sex of the respondent	1=male 2=female

Note. OQOL = Overall quality of life rating; TPHSSRC = Transformed Physical Health Scale Score with reverse coded items 3 and 4 summed; TPsychSSRC = Transformed Psychological Health Scale Score with reverse coded item 26; TSRSS = Transformed Social Relationships Summed Score (no reverse coded items); TEnvironSS = Transformed Enviromental Summed Score (no reverse coded items).

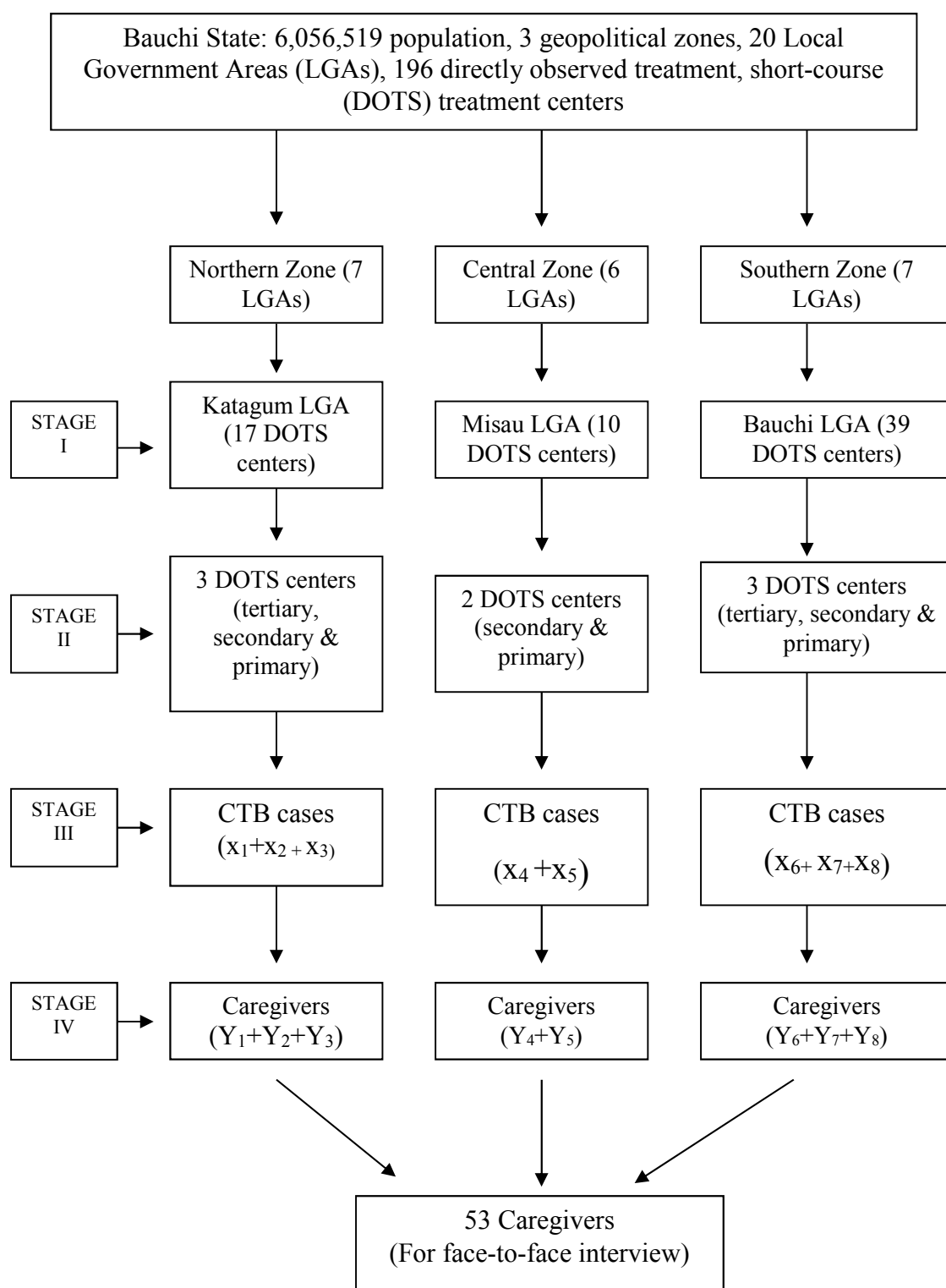


Figure 5. Illustration of multi-stage sampling technique for the study.

According to Columbia University (2015), retrospective record review is a cost-effective and efficient method to collect and analyze post exposure medical information especially because of the fact I know exactly the type of data to be extracted and how to handle missing or incomplete records in the source data base. Thus, I carried out a retrospective record review of the selected CTB records from each of the eight DOTS treatment centers in order to collect and analyze information on children who had been diagnosed with TB following exposure to the causative agent, the *mycobacterium tuberculosis* (see Figure 5).

Methodology

Population

The study population consisted of caregivers of CTB patients diagnosed from January 1, 2011 to December 31, 2015 in Bauchi State, Northeastern Nigeria. The state, nicknamed ‘Pearl of Tourism’, is one of the six states in the northeastern region of the country, divided into 20 local government areas (LGAs) with a projected population of 6,056,519 million people comprising of 51% males and 49% females (NPC, 2014). It occupies a total land area of 49,119 km², representing about 5.3% of the country’s total land mass and is located between latitudes 9° 3' and 12° 3' north and longitudes 8° 50' and 11° east. It is multiethnic and multilingual in nature with an estimated 55 tribal groups, with Hausa Language being the most widely spoken across all parts of the state.

The economy is driven essentially by agriculture and tourism apart from few manufacturing industries in iron, steel, water, ceramics, food and beverages. The vast fertile soil and water resources available in the state makes crops production and animal

husbandry the main stay of its economy, coupled with the presence of the famous Yankari Game Reserve, which is said to be the biggest game reserve in West Africa (ALL.BIZ: Nigeria, 2016).

The study sample was obtained through a multi-stage sampling technique, to be conducted in four stages (see Figure 5), culminating into the random selection of CTB cases from the 8 DOTS treatment centers: two at tertiary level, three at secondary level and three at primary level of care.

Inclusion and Exclusion Criteria for Childhood TB Cases

The inclusion criteria included a) only children aged 0-14 years old diagnosed by a physician with CTB, b) all cases would have to meet WHO/NTP case definition for CTB (CDC, 2014; WHO, 2015a), c) all cases diagnosed and treated in any of the eight selected DOTS treatment centers, and, d) all CTB cases diagnosed and treated between January 01, 2011 to December 31, 2015.

Conversely, the exclusion criteria included: a) all children outside the 0-14 year age range, b) all cases that have not met the WHO/NTP case definition for CTB, c) all CTB cases diagnosed and treated outside the NTP and/or within facilities that are not designated as DOTS treatment centers by the NTP, and, d) all CTB cases diagnosed before January 01, 2011 or after December 31, 2015.

Sample Size Determination

The sample size for the study was determined using the formula, $n = \frac{z^2 pq}{d^2}$

(Naing, Winn, & Rusli, 2006). The formula was utilized in a similar cross-sectional study conducted by Etokidem, Oparah, Asibong, Ndifon, & Nsan (2016) in order to assess the

attitude of public health workers in Calabar, Cross River State of Nigeria, towards people living with HIV/AIDS using the AIDS attitude scale. Similarly, Mugwe & Mbaja (2013) used the formula to determine the sample size in an experimental study of HIV positive patients on care and treatment in Kisumu District, Nyanza Province, Kenya.

Therefore, using the same formula $n = \frac{Z^2 pq}{d^2}$, the sample size for this study was calculated as follows:

n = minimum sample size

Z = reliability coefficient of 1.96 which tallies with a confidence level of 95%

p = proportion of Nigerian children aged 0-14 years diagnosed with TB in 2014

$q = 1 - p$

d = precision (in proportion of one; if 7%, $d = 0.07$)

Therefore,

$Z = 1.96$ (95% C.I)

$p = 6\%$ or 0.06

$q = 1 - p$; or $1 - 0.06 = 0.94$

d = precision error; $d = 7\% = 0.07$

$n = (1.96)^2 (0.06) (0.94) / (0.07)^2$; $n = 44$.

Assuming a non-response rate of 20%, the minimum required sample size was 53, where, 6% = proportion of Nigerian children aged 0-14 years diagnosed with TB in 2014 (WHO, 2015b).

Sampling and Sampling Procedure

The study population consisted of caregivers of children diagnosed with TB in Bauchi State, Northeastern Nigeria. Based on the 2006 National Population census, the state has an estimated population of 6,056,519 people in the ratio of 51% males and 49% females (NPC, 2014). The state is made up of 20 LGAs and divided into three zones namely Northern, Central and Southern zones, with each zone comprising of seven, six and seven Local Government Areas (LGA) respectively as shown in Table 7.

Table 7

Distribution of LGAs by Zone in Bauchi State, Northeastern Nigeria

Northern Zone	Central Zone	Southern Zone
Gamawa	Dambam	Alkaleri
Giade	Darazo	Bauchi
Ita Gadau	Ganjuwa	Bogoro
Jama'are	Misau	Dass
Katagum	Ningi	Kirfi
Shira	Warji	Tafawa Balewa
Zaki		Toro

Note. LGA = local government area.

In order to arrive at a representative sample of caregivers from each of these three zones, a multi-staged sampling technique, to be conducted in four stages, was employed (see Figure 5).

Stage I: Selection of Local Government Areas

Out of the 20 LGAs in the state, one LGA would be randomly selected from each zone using simple random technique: Katagum, Misau and Bauchi LGAs from Northern, Central and Southern Zones respectively (see Table 8).

Stage II: Selection of Health Facilities

As at December 31, 2015, there were a total of 1142 health facilities in Bauchi State operating at primary, secondary and tertiary levels (NPC, 2014). Out of these, only 196 offer TB services (directly observed treatment, short-course or DOTS) under the overall supervision of the NTP, Bauchi State TB control program and development partners. Thus, the selection of health facilities for this study was restricted to be from the 67 DOTS centers located in the three LGAs selected in stage I (see Table 8).

Table 8

Distribution of TB DOTS Centers in the Three Selected LGAs

	Katagum LGA	Misau LGA	Bauchi LGA	Total
Tertiary	1	0	1	2
Secondary	1	1	2	4
Primary	15	9	37	61
Total	17	10	40	67

Note. LGA = local government area.

Three facilities (TB DOTS centers) were randomly chosen from each of the three selected LGAs, giving a total of nine. However, because there is no tertiary health facility in Misau LGA, only 8 facilities would be selected. The list of the health facilities (TB

DOTS centers) in these three selected LGAs formed the sampling frame for the selection of the facilities for the study (see appendix A). Using a simple random technique, the following health facilities (TB DOTS centers) were selected from the sampling frame: Federal Medical Center (FMC), Azare (Tertiary), General Hospital (GH), Azare (Secondary) and Primary Health Center (PHC), Bulkachuwa in Katagum LGA; General Hospital, Misau (Secondary) and Primary Health Centre, Hardawa (Primary) in Misau LGA; and Abubakar Tafawa Balewa University Teaching Hospital (ATBUTH), Bauchi (Tertiary), Infectious Diseases Hospital (IDH), Bayara (Secondary) and Primary Health Center, Tashan Babiye (Primary) in Bauchi LGA.

Stage III: Selection of Case Files.

Due to the variations in the number of CTB cases diagnosed in each of the eight selected TB DOTS centers, case records selection was done through a proportional probability sampling (PPS) technique, using as the sampling frame, all the CTB cases diagnosed in the eight selected DOTS treatment centers from January 1, 2011 to December 31, 2015.

For instance, assuming that $x_1, x_2, x_3, x_4, x_5, x_6, x_7$, and x_8 denotes the proportions of CTB records selected from each of the 8 DOTS treatment centers; number of CTB cases diagnosed from January 1, 2011 to December 31, 2015 in each of the 8 DOTS treatment centers is represented as $x(a), x(b), x(c), x(d), x(e), x(f), x(g)$, and $x(h)$; total number of CTB cases diagnosed from January 1, 2011 to December 31, 2015 in all the 8 DOTS treatment centers is represented as X ; then the proportion of CTB

records to be selected for review from each of the eight selected DOTS treatment centers would be determined as

$$x_1 = \frac{x(a)}{X} \times Y, x_2 = \frac{x(b)}{X} \times Y, x_3 = \frac{x(c)}{X} \times Y, x_4 = \frac{x(d)}{X} \times Y, x_5 = \frac{x(e)}{X} \times Y,$$

$$x_6 = \frac{x(f)}{X} \times Y, x_7 = \frac{x(g)}{X} \times Y \text{ and } x_8 = \frac{x(h)}{X} \times Y$$

Where $x(a)$ = number of CTB cases recorded in Federal Medical Center, Azare, from 2011 to 2015,

$x(b)$ = number of CTB cases recorded in General Hospital, Azare, from 2011 to 2015,

$x(c)$ = number of CTB cases recorded in Primary Health Center, Bulkachuwa, from 2011 to 2015,

$x(d)$ = number of CTB cases recorded in General Hospital, Misau, from 2011 to 2015,

$x(e)$ = number of CTB cases recorded in Primary Health Center, Hardawa, from 2011 to 2015,

$x(f)$ = number of CTB cases recorded in ATBUTH, Bauchi, from 2011 to 2015,

$x(g)$ = number of CTB cases recorded in IDH Bayara, from 2011 to 2015,

$x(h)$ = number of CTB cases recorded in Primary Health Center, Tashan Babiye, from 2011 to 2015,

X = total number of CTB cases diagnosed from January 1, 2011 to December 31, 2015 in all the eight selected DOTS treatment centers, and

$$= x(a) + x(b) + x(c) + x(d) + x(e) + x(f) + x(g) + x(h)$$

Y = Target population size of the study (53) determined using the formula,

$$n = \frac{Z^2 pq}{d^2}$$

For each DOTS treatment center, the CTB cases diagnosed from January 1, 2011 to December 31, 2015 were used as the sampling frame for the systematic sampling of case records to be reviewed. This was done by randomly choosing from within the first to the sixth case record (X/Y) from then onwards, where $X = 338$ and $Y = 53$. The case records sampled from each center were retrieved and compiled to arrive at the required sample size of 53. The case records that were proportionally sampled from each center were thus: FMC Azare (43), GH Azare (3), PHC Bulkachuwa (0), GH Misau (14), PHC Hardawa (0), ATBUTH Bauchì (242), IDH Bayara (34) and PHC Tashan Babiye (2).

Stage IV: Selection of Study Population (Caregivers)

Each of the CTB cases selected from these eight DOTS treatment centers should have a parent and/or a caregiver whose information could be found in the patient's case file. This information was obtained for each case, added up and constituted the study population of this research work. A line list of all the 53 randomly selected caregivers was made and they were contacted by mail at their various addresses and recruited for the interview, subject to fulfilling all the laid down ethical standards and protocols.

Procedures for Data Collection

In each of the eight directly observed treatment, short-course (DOTS) treatment centers selected, confirmed CTB cases can be found in the facility register (NTBLCP/TB

08). Permission was sought from Bauchi State Ministry of Health's Research Ethics Committee (HREC), after providing written assurances that the study would be strictly for academic research purposes and that its outcomes would be meted with utmost confidentiality. The ministry was further assured that identifiers such as the name of CTB patients, their parents and/or caregivers, addresses were coded to safeguard against identification by people outside the research community. Second, I interviewed a very limited number of caregivers of the sampled CTB cases and measured their QOL, SES and gender. Each of the participants was adequately informed about the study to enable him/her decide whether to participate or not. For those who agree to participate, a written consent was obtained from each one of them in line with ethical standards.

Childhood TB Data Collection Procedure

The CTB data required for this study was obtained from the tool NTBLCP/TB 08, available in each of the eight selected DOTS treatment centers. I extracted the required data from the NTBLCP/TB 08 and transferred it to the form in appendix B, a tool modified with permission from a similar survey by Saleh (2014). The form, which was applied one per facility, thus contained the total number of CTB cases aged 0-14 years that were notified to the NTP from January 1 2011 to December 31 2015. The form contained three types of information collected from each case extracted: unique Local Government Area TB Identification Number (LGA TB ID No.), Date of Birth (DOB) and sex. The extracted data from each center was then summarized for each year, using the form in appendix C, also modified with permission from Detjen, Grzemska, Graham, and Sismanidis (2012).

DOTS Treatment Center Retrospective Record Review Procedure

Appendix B was used to compile all the CTB cases diagnosed from January 01, 2011 to December 31, 2015 in each of the eight selected directly observed treatment, short-course (DOTS) treatment centers facilities.

Appendix C was used to summarize these cases. Each of the patients that had been extracted had a case file and/or a treatment card, depending on whether he/she had been on admission while on treatment or was treated on outpatient basis. Each of the case files and/or treatment cards extracted had the unique LGA TB ID No. which was used during the random selection of the required number of cases from each of the eight DOTS treatment centers.

Accuracy Verification Procedure

In order to assure that the CTB retrospective dataset(s) are accurately transferred and analyzed, the data extracted was checked for accuracy and inconsistencies through techniques like double entry, proof reading and reviewing against its original source. This is to ensure that it was accurately transferred from its original source to the forms in appendix B and C, there by identifying areas of disparity (if any), averting any erroneous data loss, and ensuring that all the extracted cases are true CTB cases diagnosed based on the WHO/NTP criteria.

The verified case files/treatment cards were studied and the identifying information of the caregiver of the patient teased out. Using the patient's address and other contact information such as mobile phone number (if available), the caregiver was traced and the consent for the interview obtained. The survey questionnaire, was applied

and information about the independent variables (QOL, SES, and gender of caregivers) was obtained for each respondent using WHOQOL-BREF questionnaire, obtained with kind permission from the WHO (Appendix D).

Pilot Study

A pilot study was planned to be conducted in a DOTS treatment center other than any of the eight selected centers, using 6 randomly selected CTB case files to retrieve the corresponding 6 caregivers who would not be included in the proper study. I was to administer the study instruments (the tools in Appendices B and C and the WHOQOL-BREF questionnaire) on the 6 caregivers so as to develop and test their suitability, assess the possibility of the impending full-scale study, assess whether the research protocol was accurate and practicable, assess the likely success of proposed recruitment approaches and finally identify logistical problems which might occur using proposed methods (van Teijlingen & Hundley, 2001).

Instrumentation and Operationalization of Constructs

The form in appendix B was very suitable for the study as it was used to line list, on year by year basis, all the extracted childhood cases from the TB facility registers (NTBLCP/TB 08) in each of the eight selected directly observed treatment, short-course (DOTS) treatment centers. The format of the form is modified to accommodate the abstracted CTB cases for the purpose of this study, since CTB program data is recorded and reported on quarterly basis at all levels, and health facilities (DOTS treatment centers) remain the basic unit of data in Nigeria (FMOH, 2014). The original instrument was used by Saleh (2014) to determine the prevalence of another communicable disease,

neonatal tetanus, also in Northeastern Nigeria. Apart from determining the NNT prevalence at 28.8%, the study ascertained reasons for Nigeria's failure to meet the deadline of the global NNT elimination strategic plan. Permission to modify and use the instrument for this study was obtained from the author.

Appendix C was used to summarize all the eight filled appendix B forms into one. It was a modified version of an instrument used by Detjen et al. (2012), in improving the estimates of CTB disease burden and assessing CTB activities at country level. The survey was a collaborative effort between the WHO Stop TB Department Geneva, the Stop TB Partnership Secretariat Geneva and The International Union against Tuberculosis and Lung Disease (IUATLD), Paris. Nigeria was among the 10 TB high burden countries that participated in the survey, as such, the adoption of the form was deemed appropriate since it had been successfully applied in the country. However, the form had to be modified in order to accommodate the variables reported in the previous tool and to collate and summarize the entire data collected from the eight selected facilities.

Interview of the Caregivers

Face to face interview of the care-givers was conducted using a well-tested, valid and reliable tool, the WHOQOL-BREF questionnaire, The WHOQOL-BREF questionnaire is a valid tool which had been used by to measure the QOL of several categories of research subjects. For instance, Adebowale, Atte, and Ayeni (2012) used it to measure the QOL of the elderly people in a rural community in North Central Nigeria. Apart from measuring QOL, this tool helped the authors in identifying predictors of

elderly well-being to be age, children ever born, children alive, marital status, financial support from children, children visit by gender, children living with elderly and having enough money to meet daily needs.

Likewise, using the same tool in this study was helpful in determining the QOL, socio-economic status and gender of caregivers and relating these with the reporting of CTB in Bauchi State, Northeastern Nigeria. Subject to obtaining a written informed consent from each participant, I administered the questionnaire individually so as to ensure that valid and reliable results were obtained. Three independent variables: QOL, socio-economic status and gender were measured from the respondents. The QOL of each respondent was measured through two individually scored items about the respondent's overall perception of QOL and health as well as through four domain scores which were scaled in a positive direction from 1 to 5, with higher score indicating a higher QOL, except for 2 items in domain one and 1 item in domain two that had to be reversed before scoring ; their SES was measured using their educational status, since it was the only SES variable in the questionnaire; their gender was measured as a categorical variable, either male or female (see Table 6).

Data Analysis

Data generated for this study was analyzed using SPSS version 21 to address the following research questions and hypotheses:

RQ1: Is caregivers' QOL related to the reporting of CTB?

Ho1: Caregivers' QOL is not related to the reporting of CTB.

Ha1: Caregivers' QOL is related to the reporting of CTB.

RQ2: Is caregivers' gender related to the reporting of CTB?

H₀₂: Caregivers' gender is not related to the reporting of CTB.

H_{a2}: Caregivers' gender is related to the reporting of CTB.

RQ3: Is caregivers' SES related to the reporting of CTB?

H₀₃: Caregivers' SES is not related to the reporting of CTB.

H_{a3}: Caregivers' SES is related to the reporting of CTB.

Demographic characteristics of the respondents such as gender, age, marital and educational status were analyzed. The relationships between the independent variables, i.e. caregivers' QOL, SES and gender, and the reporting of CTB was determined by MLR model including adjusted odds ratios and related 95% confidence intervals. The reporting of CTB was measured as a dichotomous variable where 0 = no TB and 1 = TB present. Therefore, based on the sample size calculation above, 53 CTB cases and 53 controls were selected.

The assumptions for this test include the fact that the dependent variable is dichotomous, and has been coded as such; all the variables in the WHOQOL-BREF questionnaire would be included in the analyses; the independent variables are independent of each other; the independent variables are linearly related to the log of the odds ratio; and the fact that an adequate sample size would be calculated. All these assumptions were met.

Threats to Validity

According to Frankfort-Nachmias and Nachmias (2008), the validity of a research study design can either be internal or external. Internal validity is achieved when the

researcher does all the needful “to rule out other factors as rival explanations of the observed association between the variables under investigation” (Frankfort-Nachmias & Nachmias, 2008, p. 95). In other words, internal validity is accomplished when the study deduces that the changes in the independent variables did, in fact, cause the dependent variable to change. Conversely, external validity of a design is “the extent to which research findings can be generalized to larger populations and applied to different social and political settings” (Frankfort-Nachmias & Nachmias, 2008, p. 101).

Internal Validity

In this study, one potential threat to internal validity is selection bias in view of the fact that knowledge gap among the different cadres of clinicians involved in the diagnosis and management of CTB cases could lead to misdiagnosis of the cases recorded in the selected health facilities. This is even more so considering the fact that the eight facilities selected exist in all the three levels of care: tertiary, secondary and primary, with the latter having the least educated clinicians. In this study, selection bias was addressed by ensuring the random selection of both children with TB and children without TB in each of the eight selected health facilities (Frankfort-Nachmias & Nachmias, 2008).

Another potential threat to internal validity for this study is the so-called instrumentation bias, which may occur when after the administration of the data collection instruments (forms in appendix B and C) by the researcher, the results become inconsistent as changes may have occurred during the study in the way the variables were

measured. However, considering the fact that these instruments had already been validated by other researchers, instrumentation bias may not be an issue after all.

External Validity

Lastly, the extent to which the study findings can be generalized to larger populations (external validity) largely depended on how big the sample size was as well as the response rate for the face-to-face interview with the caregivers. This threat was addressed by limiting generalizations to simpler populations from which the study sample was drawn.

Ethical Procedures

It is clear that this study intends to officially obtain approval to gain access to a five-year data on diagnosed CTB cases from Bauchi State Ministry of Health. In addition, an approval to conduct the study was also sought from the Walden University IRB. After securing these approvals, data collection then commenced: the data was retrospectively reviewed, collected, and sampled to arrive at the calculated sample size. The caregivers of these sampled CTB cases formed the study participants. Those caregivers who consented to participating were interviewed face-to-face using the WHOQOL-BREF questionnaire. Finally, in line with the declaration made by the WMA during its 18th General Assembly in Helsinki, Finland, June 1964, and amended during its 64th WMA General Assembly, Fortaleza, Brazil, October 2013, all sets of ethical principles guiding medical research involving human subjects were observed (WMA, 2016).

These principles include, but limited to, ensuring that all the electronic data obtained from the data base and those to be generated from the study participants are pass

worded and kept in a laptop computer to avoid unauthorized access. Similarly, all the paper based and electronic data, including the questionnaires used and/or a flash drive were properly filed and kept under lock and key in my home. Finally, upon completion of the study, the data would be retained for five years, and destroyed afterwards in line with international best practice.

Summary

The purpose of this observational cross-sectional study was to determine the relationship between QOL, SES and gender of caregivers and the reporting of TB in their children in Bauchi State, Northeastern Nigeria. Retrospective review of records of CTB records between January 01, 2011 and December 31, 2015 was conducted. Out of the total number of CTB cases extracted, an effective sample size was scientifically determined using a statistical formula. The caregivers of these sampled CTB cases were the study participants and were interviewed face to face using the WHOQOL-BREF questionnaire after having obtained their informed consent.

Chapter 3 has explained the proposed study design, including the independent and dependent variables. Furthermore, it has given an account of the study population, sampling strategy, sample size estimation, data collection procedure, instrumentation and operationalization of constructs, statistical tests and data analysis plan, threats to validity, and ethical procedures.

Chapter 4: Results

Introduction

The purpose of this study was to explore the relationship between caregivers' QOL, SES, gender and reporting of CTB in Bauchi State, Northeastern Nigeria. This chapter previews the research questions and hypotheses, the demographic characteristics of the respondents, the results of the entire study, and a summary of the key outcomes of this research. The research questions and hypotheses that informed the study are as follows:

RQ1: Is caregivers' QOL related to the reporting of CTB?

Ho1: Caregivers' QOL is not related to the reporting of CTB.

Ha1: Caregivers' QOL is related to the reporting of CTB.

RQ2: Is caregivers' gender related to the reporting of CTB?

Ho2: Caregivers' gender is not related to the reporting of CTB.

Ha2: Caregivers' gender is related to the reporting of CTB.

RQ3: Is caregivers' SES related to the reporting of CTB?

Ho3: Caregivers' SES is not related to the reporting of CTB.

Ha3: Caregivers' SES is related to the reporting of CTB.

Data Collection

Data collection commenced in the second week of February 2017, immediately after receiving IRB approval from Walden University. Archival CTB data for the period January 2011 to December 2015 belonging to the eight selected health facilities were accessed at the Bauchi State Ministry of Health. For each CTB case reported within the

period, the researcher included information on the unique Local Government Area TB Identification Number (LGA TB ID No.), date of birth (DOB), and sex using the survey instrument in appendix B. One form was used per health facility, resulting in eight filled forms. These forms were summarized into a single form shown in appendix C. As can be seen from Table 9, a total of 338 CTB cases were identified from the eight health facilities selected. The researcher visited each of these facilities and picked out the case file and treatment card of each of these cases and kept them under lock and key. The total number of case files and treatment cards in each health facility formed the sampling frame of the study from which the required CTB cases were proportionately calculated out of the known sample size of 53 CTB cases. The number of CTB cases to be contributed by each health facility to make up the sample size was obtained using the systematic random sampling technique (Martínez-Mesa, González-Chica, Duquia, Bonamigo, & Bastos, 2016).

Table 9

Number of CTB Cases Extracted and Sampled from Each Health Facility

S/N	Health Facility	CTB Cases Extracted	CTB Sampled	Caregivers Identified
1	FMC Azare	43	6	6
2	GH Azare	3	1	1
3	PHC Bulkachuwa	0	0	0
4	GH Misau	14	2	2
5	PHC Hardawa	0	0	0
6	ATBUTH Bauchi	242	38	38
7	IDH Bayara	34	5	5
8	PHC Tashan Babiye	2	1	1
Total		338	53	53

Having proportionately sampled the CTB cases from each health facility, the researcher used the case file/treatment card of each of the sampled 53 CTB cases and identified their corresponding caregivers who eventually became the research participants. Thereafter, the researcher ensured that all of them had met the inclusion criteria: caregivers of children aged 0-14 years old diagnosed with TB by a physician according to the NTP/WHO guidelines as retrieved from the selected case files, caregivers of CTB cases diagnosed and treated in any of the eight selected TB DOTS treatment centers between January 01, 2011 to December 31, 2015 in Bauchi State, Northeastern Nigeria, and caregivers of both sexes ages 18 years and above.

An invitation letter (see appendix F) was mailed to each of the 53 sampled participants, requesting for their voluntary participation in the research study.

Furthermore, in order to assist everyone in reaching an informed decision on whether to

participate or not, a copy of the consent form with detailed information about the study was attached to the invitation letter. Thus, a total of 47 invited participants (88.7%) agreed to participate and were interviewed by the researcher face to face in their communities of residence after signing an informed consent form. Each interview session lasted 15 minutes on average, while it took a period of 3 weeks for all the consenting participants to be interviewed.

The WHOQOL-BREF questionnaire was used to interview each participant. It comprises of 26 questions, 24 of which are spread in four domains: physical, psychological, social relations, and environment. These domains consisted of seven, six, three, and eight questions respectively. The questions were measured on a five-point scale ranging from 1 to 5. The domain scores were scaled in a positive direction. The overall well-being of the respondents was dichotomized into poor or good based on WHO standard procedures. The remaining two questions are general: One linked to the self-perceived QOL and the other to contentment with health. Overall, there were no major difficulties faced by the researcher during the data collection process and there were no modifications in the study methodology described in Chapter 3.

Data analyses was done with the help of SPSS. The data had been compiled in an excel spread sheet. This was converted into an SPSS format and the variables were manually coded. Summed scale scores for all the items within the QOL measure were created. Additionally, transformed scale scores were also created as per the scoring instructions provided on the WHO-QOL BREF questionnaire. These were the scores used in the analysis.

Demographic Characteristics of the Sample

The target population for the study were caregivers of CTB cases diagnosed between January 01, 2011 to December 31, 2015 in Bauchi State, Northeastern Nigeria. Caregivers' data was collected during face to face interviews conducted on 47 caregivers of randomly sampled CTB cases, after having signed informed consent forms. Similarly, I collected data in the same manner from another set of 47 caregivers of children diagnosed with ailments other than TB within the same period and in the same eight health facilities for the purpose of comparison. Thus, all in all, I interviewed a total of 94 caregivers of children with and without TB using the WHOQOL-BREF questionnaire.

The demographic data I collected include gender, age, marital and educational status of respondents. As shown in Table 10, majority of the respondents in both groups were males (63.8% and 57.4%), young within the reproductive age group of 18-49 years (76.6% and 80.8%) and married (80.9% and 83.9%). However, respondents whose children had no TB appear to be more educated, as 34 of them (72.4%) either attended high school or college, than those whose children had TB, where less than half of them (23 or 49%) attended either high school or college as shown in Table 10.

Table 10

Demographic Characteristics of Respondents

Demographics		Number of Children with TB	Number of Children without TB	% Children with TB	% Children without TB	Total
Gender	Male	30	27	63.8	57.4	57
	Female	17	20	36.2	42.6	37
Age	18-29	15	16	31.9	34.0	31
	30-39	13	12	27.7	25.5	25
	40-49	8	10	17.0	21.3	18
	50-59	7	8	14.9	17.0	15
	60+	4	1	8.5	2.1	5
Marital Status	Single	4	3	8.5	6.4	7
	Married	38	39	80.9	83.0	77
	Divorced	2	2	4.3	4.3	4
	Widowed	3	3	6.4	6.4	6
Educational Status	None	6	4	12.8	8.5	10
	Elementary	18	9	38.3	19.2	27
	High School	13	20	27.7	42.6	33
	College	10	14	21.3	29.8	24

In order to perform a logistic regression analysis, I needed a similar sample of children who do not have TB, so that the dependent variable would become dichotomous (Field, 2013). Thus, in each of the eight selected health facilities, I reviewed the outpatient department (OPD) register, and extracted information on children aged 0-14 years who had been diagnosed with any childhood illness other than TB within the period January 1, 2011 to December 31, 2015, taking care to match the age and gender of these children with those of the CTB cases. Each of the 47 CTB cases was thus paired with a non-TB child patient resulting in the extraction of a total of 47 childhood non-TB patients as controls. Accordingly, I traced, invited and interviewed the caregivers of these control

cases face to face, using the same WHOQOL-BREF questionnaire. Thus, the data obtained from all the 94 interviewed caregivers was subjected to logistic regression analysis using the SPSS as shown in Table 11. As can be seen, there were two types of respondents: 47 (50%) respondents were caregivers whose children do not have TB and 47 (50%) were caregivers whose children were diagnosed with TB. There were no missing data: there were equal number of respondents in each of the two groups of interviewees, no TB and TB present respectively.

Table 11

Presence of TB among the Children of Respondents

		Frequency	Percent	Valid Percent	Cumulative %
Valid	No TB	47	50.0	50.0	50.0
	TB present	47	50.0	50.0	100.0
	Total	94	100.0	100.0	

To address the research questions, frequency, descriptive statistics and logistic regression were conducted with the help of SPSS. The data, which had been compiled in an excel spread sheet was converted into an SPSS format and the variables manually coded. Summed scale scores for all the items within the QOL measure were created. Additionally, transformed scale scores were also created as per the scoring instructions provided on the WHO-QOL BREF questionnaire. These were the scores used in the analysis. The values of $p < .05$ were considered significant.

As shown in Table 12, the mean and standard deviation (SD) for overall QOL rating as well as for those of the other four QOL domains for the respondents (each of the

two groups separately and then combined) have been determined with the help of SPSS. For instance, the overall QOL rating for respondents whose children do not have TB appears to be higher (mean 7.87 and SD 1.84) as compared with that of respondents whose children have TB (mean 6.85 and SD 1.37). This difference was statistically significant ($p < .01$) as shown in Table 12. Likewise, the scores for each of the four QOL domains were higher in respondents whose children do not have TB than in respondents whose children have TB and these differences were statistically significant ($p < .01$). These findings suggest that respondents whose children do not have TB have higher QOL than those whose children have TB. Additionally, Figure 6 is a histogram showing the overall QOL rating. As can be seen, the distribution is unimodal (one peak) and appears symmetric even though the bulk of the data is at the right and the left tail is longer (skewed left or negatively skewed).

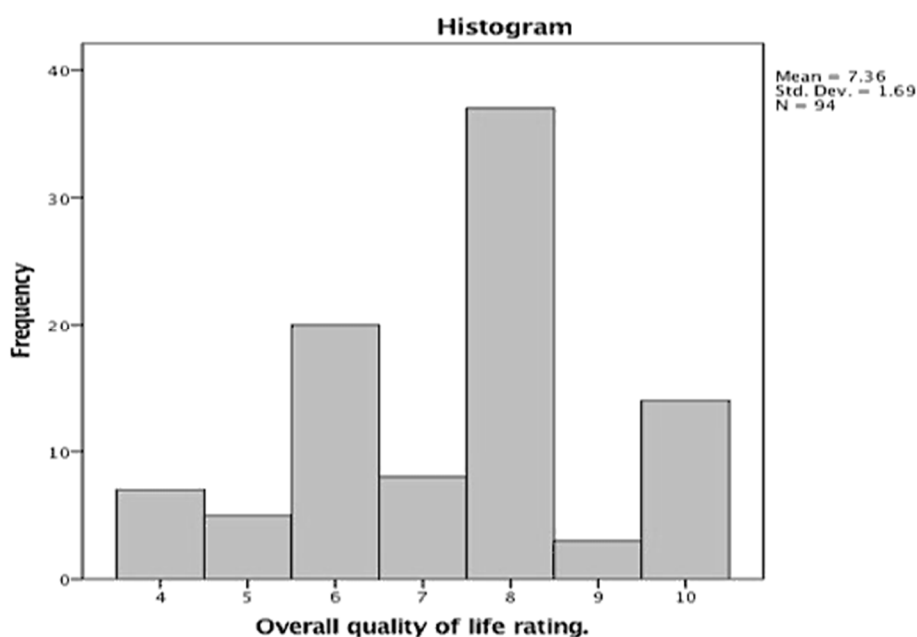


Figure 6. Histogram showing the overall QOL scores for the respondents.

Table 12

WHOQOL Scale Table of Means for Children With and Without TB

	Children with TB		Children without TB		Total		p-value
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	
Overall QOL Rating	6.85	1.367	7.87	1.837	7.36	1.690	.003
Physical Health Scale Score (Transformed)	58.51	11.38	72.26	20.89	65.39	18.11	.000
Psychological Health Scale Score (Transformed)	55.14	11.53	63.65	15.80	59.40	14.41	.004
Social Relationships Score (Transformed)	57.09	15.44	67.73	14.50	62.41	15.83	.001
Environmental Score (Transformed)	47.88	11.51	69.15	14.71	58.51	16.94	.000

The Assumption of Normality of the Data

For this study, the goals of performing normality tests were to test if the study sample conforms to normality assumptions as well as to assess the normality for the continuous scale variables used in the regression analysis. In other words, which of them were normally distributed and which of them were not. Normally distributed data imply

that an inference could be made about the population from which the sample of data was collected.

Thus, as can be seen in Table 13, the Kolmogorov-Smirnov (K-S) test for normality of data showed that in two out of the four domain scores (physical and psychological), the significance values of the test was 0.200, which is $>.05$ indicating that the data is normally distributed. For the other two domain scores (social relations and environment), the significant value of the test was .000, which is $<.05$, meaning that the sample of data collected was not normally distributed. However, this is not worrisome as the sample size in the two groups was more than 30 each, in accordance with the central limit theorem, which states that as long as the sample is based on 30 or more observations, the data can be safely assumed to be normal (Field, 2013).

Table 13

Tests of Normality of Data

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig. .	Statistic	df	Sig.
Overall QOL rating	.222	94	.000	.910	94	.000
Physical Health Scale Score w/ Reverse Coded Items 3 and 4 Summed	.074	94	.200*	.974	94	.062
Transformed Physical Health Scale Score w/ Reverse Coded Items 3 and 4	.074	94	.200*	.974	94	.062
Psychological Health Scale Score w/ Reverse Coded Item 26 Summed	.075	94	.200*	.980	94	.164
Transformed Psychological Health Scale Score w/ Reverse Coded Item 26	.075	94	.200*	.980	94	.164
Social Relationships Summed Score; No Reverse Scored Items	.180	94	.000	.954	94	.002
Transformed Social Relationships Summed Score; No Reverse Coded Items	.181	94	.000	.954	94	.002
Environmental Summed Score; No Reverse Coded Items	.143	94	.000	.955	94	.003
Transformed Environmental Summed Score; No Reverse Coded Items	.143	94	.000	.955	94	.003

Logistic Regression for Research Question 1

Before commencing the analyses for each research question, I ensured that all the assumptions for logistic regression analyses were met. These include: the dependent variable was dichotomous; the dependent variable was coded accordingly (children with TB=1, children without TB=0); all the variables in the WHOQOL-BREF questionnaire were included in the analyses; the independent variables are independent of each other; the independent variables are linearly related to the log of the odds ratio; and finally the large sample size of 94 respondents.

RQ1: How is caregivers' QOL related to the reporting of CTB?

Ho1: Caregivers' QOL is not related to the reporting of CTB.

Ha1: Caregivers' QOL is related to the reporting of CTB.

Using SPSS version 21, a simple logistic regression analysis was done in order to determine how well caregivers' overall QOL (transformed scores on physical health, psychological health, social relationships, and environmental factors), gender and SES (using educational status) predict their likelihood to report the presence of TB in their children. Despite the fact that the data for physical and psychological health domains were earlier shown to be normally distributed, I used the transformed scores on both domains as well as on the other two domains in accordance with WHOQOL-BREF questionnaire scoring instructions stipulating that only transformed scores should be used for analysis (WHOQOL, 1994).

Thus, as shown in Table 14, there are 94 cases in the data set and there are no missing values. It also shows that 100% of cases are represented in the regression analysis.

Table 14

Case Processing Summary

Unweighted Cases ^a		N	Percent
Selected Cases	Included in Analysis	94	100.0
	Missing Cases	0	.0
	Total	94	100.0
Unselected Cases		0	.0
Grand Total		94	100.0

Furthermore, as can be seen in Table 15, out of the 94 respondents in the dataset, 47 of them (50%) have TB in their children, while the remaining 47 have no TB in their children.

Table 15

Classification Table^{a,b}

			Predicted Presence of TB		
Observed			No TB	TB	% Correct
Step 0	Presence of TB	No TB	0	47	.0
		TB present	0	47	100.0
Overall Percentage					50.0

a. Constant is included in the model.

b. The cut value is .500

Table 16 shows that only two out of the four QOL domain variables made a significant contribution to the model-the transformed social relationships summed score,

TSRSS, ($p < .01$) and the transformed environmental summed score, TEnviroSS, ($p < .001$). The adjusted odds ratio (OR) for TSRSS was 1.20 indicating that there was a statistically significant difference between the QOL of caregivers whose children have TB with those whose children do not have TB. Furthermore, since the OR is > 1 , then the group of caregivers whose children do not have TB have higher levels of satisfaction with their social relationships by 20% than the group of caregivers whose children have TB.

Conversely, the adjusted OR for TEnviroSS was 0.65, which is less than 1, indicating that caregivers whose children do not have TB have lower levels of satisfaction with their environment by 35% than those caregivers whose children have TB. It is noteworthy that in both domains, the confidence intervals (CI) are small, indicating a higher precision of the OR. The other two QOL domain variables did not make a significant contribution to the model-physical health and psychological health ($p > .05$). Thus, we have established that caregivers' QOL variables (especially the social relationship and environment domains) are related to the reporting of TB in their children, and can reject the null hypothesis.

Logistic Regression for Research Question 2:

RQ2: How is caregivers' gender related to the reporting of CTB?

H₀₂: Caregivers' gender is not related to the reporting of CTB.

H_{a2}: Caregivers' gender is related to the reporting of CTB.

Table 16 shows that for the categorical variable of gender, the significance of the Wald (0.821), the Exp(B) (.855), and the 95% Confidence Intervals for Exp(B) (.220 to

3.326). The Exp(B) of .855 is the adjusted odds ratio indicating some relationship between gender of caregivers and the reporting of TB in children. However, this relationship is not statistically significant because the p value is $>.05$, and the confidence interval includes 1. Thus, it can be concluded that the relationship between caregivers' gender and the reporting of CTB is not statistically significant, there by accepting the null hypothesis.

Logistic Regression for Research Question 3:

RQ3: How is caregivers' socio-economic status related to the reporting of CTB?

H₀₃: Caregivers' socio-economic status is not related to the reporting of CTB.

H_{a3}: Caregivers' socio-economic status is related to the reporting of CTB.

Table 16 shows that the variable of education, which was used as a sole measure for socio-economic status of the caregivers (since the WHOQOL-BREF questionnaire does not contain the other two variables for measuring socio-economic status, namely income and occupation) did not make a significant contribution to the model-education, education (1), education (2) and education (3) because $p > 0.05$ in all of them. Thus, it can be concluded that the relationship between caregivers' SES and the reporting of CTB is not statistically significant, there by accepting the null hypothesis.

Table 16

Variables in the Equation

Step 1 ^a	B	S.E.	Wald	df	Sig.	95% C.I. for Unadjusted OR			95% C.I. for Adjusted OR		
						Exp(B)	Lower	Upper	Exp(B)	Lower	Upper
Gender (1)	.157	.693	.051	1	.821	1.170	.301	4.550	.855	.220	3.326
Education			4.270	3	.234						
Education (1)	2.761	1.506	3.360	1	.067	15.812	.826	302.679	.009	.000	2.072
Education (2)	2.714	2.063	1.730	1	.188	15.089	.264	861.150	.140	.005	4.099
Education (3)	4.728	2.784	2.884	1	.089	113.075	.483	26492.696	.133	.012	1.548
OQOL	.318	.705	.203	1	.652	1.374	.345	5.471	1.374	.345	5.471
TPHSSRC	.109	.065	2.781	1	.095	1.115	.981	1.267	1.115	.981	1.267
TPsyehSSRC	-.062	.060	1.044	1	.307	.940	.836	1.058	.940	.836	1.058
TSRSS	.182	.067	7.439	1	.006	1.200	1.053	1.367	1.200	1.053	1.367
TEnviroSS	-.433	.122	12.582	1	.000	.648	.510	.824	.648	.510	.824
Constant	6.208	2.614	5.640	1	.018	496.619					

a. Variable(s) entered on step 1: Gender, Education, OQOL, TPHSSRC, TPsyehSSRC, TSRSS, TEnviroSS, OQOL = Overall quality of life rating, TPHSSRC = Transformed Physical Health Scale Score with reverse coded items 3 and 4, summed, TPsyehSSRC = Transformed Psychological Health Scale Score with reverse coded item 26, TSRSS = Transformed Social Relationships Summed Score (no reverse coded items.) TEnviroSS = Transformed Environmental Summed Score (no reverse coded items).

Logistic Regression for the Entire Model

For the entire model depicted on page 65, logistic regression analysis was done in order to demonstrate how well the variables gender, education, overall QOL, and transformed scores on physical health, psychological health, social relationships, and environmental factors of caregivers predict their likelihood to report the presence of TB amongst their children. As shown in Table 17, the full model containing all of the predictors was statistically significant, $\chi^2 (9, N = 94) = 72.398, p < .001$.

Table 17

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	72.398	9	.000
	Block	72.398	9	.000
	Model	72.398	9	.000

This result was supported by the significance of the Hosmer and Lemeshow test, $p = .256$ as shown in Table 18.

Table 18

Hosmer and Lemeshow Test

Step	Chi-square	Df	Sig.
1	10.129	8	.256

Finally, as shown in Table 19, the model as a whole explained between 54% (Cox & Snell R Squared) and 72% (Nagelkerke R Squared) of the variance in reported presence of TB amongst the children of these caregivers.

Table 19

Model Summary

Step	-2 Log Likelihood	Cox & Snell R Square	Nagelkerke R Square
1	57.914 ^a	.537	.716

This indicates that the model of independent variables was better able to distinguish between those who did and did not report the presences of TB amongst their children.

Summary

In this chapter, I have presented the results of my study, including demographic characteristics of the sample, frequency and descriptive statistics on all the variables within the data set, normality for the continuous scale variables used in the regression analysis and data analysis for the research questions. The data collected was subjected to appropriate statistical tests in order to determine how well do the variables gender, SES (education), overall QOL, and transformed scores on physical health, psychological health, social relationships, and environmental factors of caregivers predict their likelihood to report the presence of TB within their children. The full model containing all of the predictors was statistically significant, $\chi^2 (9, N = 94) = 72.398, p < .001$. This result was supported by the significance of the Hosmer and Lemeshow test, $p = .256$.

Evaluating the three research questions separately, however, revealed that only the findings of research question 1 showed significant relationship between caregivers'

QOL and the reporting of CTB ($p < .001$), thereby rejecting the null hypothesis. The findings of research questions 2 and 3 showed insignificant relationship of caregivers' gender ($p > 0.05$) and SES ($p > 0.05$) to the reporting of TB in their children, thereby accepting the null hypothesis in both situations. Chapter 5 will present the discussion and interpretation of the study findings as well as its limitations, recommendations and the implications for positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

Children accounted for 10% of the global TB burden in 2014, yet they remain relatively neglected in TB prevention and control efforts (Daniel et al., 2015; Erkens et al., 2014; Hamzaoui et al., 2014; Swaminathan & Rekha, 2010; WHO, 2013a). This observational cross-sectional study was undertaken with the sole purpose of exploring the possible relationship between the reporting of TB in children aged 0-14 years, and the QOL, gender, and SES of their caregivers aged 18 years and above. The study findings may address the established paucity of research studies that examine the relationship between reporting of CTB and variables pertinent to caregivers of young children in Nigeria.

The TRA/TPB was used as a guide for this study. The purpose of the study was met through face to face interviews with both caregivers of children with TB and caregivers of children without TB, administered using the WHOQOL-BREF questionnaire. Variables measured were QOL, gender, and SES of the caregivers in both groups. Demographic characteristics of the caregivers in both groups were also measured using the same tool. Descriptive and inferential statistics were used to answer all three research questions separately and in combination.

Analysis of the demographic characteristics of the caregivers in both groups revealed that the majority of them were males (63.8% and 57.4%). This finding contrasts with similar studies that showed a majority of the caregivers of children with chronic diseases to be females (Vanz et al., 2015; Kumar et al., 2012). Furthermore, majority of

the caregivers in both groups were young within the 18-49 age group (76.6% and 80.8%) and married (80.9% and 83.9%). However, caregivers of CTB cases had a lower literacy level (as only 49% of them attended either high school or college) compared with the control group, where 72.4% of them attended either high school or college. These findings were similar to those discovered in India and Egypt that also found low literacy levels among caregivers of CTB cases (Abd Allah, 2014; Jani et al., 2015).

Findings from descriptive statistics showed that the overall QOL for respondents whose children do not have TB appears to be higher (mean 7.87 and SD 1.84) compared with respondents whose children have TB (mean 6.85 and SD 1.37). This difference was statistically significant ($p < .01$). Likewise, the scores for each of the four QOL domains were higher in respondents whose children do not have TB than in respondents whose children have TB and these differences were statistically significant ($p < .01$). These findings suggest that respondents whose children have TB have impaired QOL compared with those whose children do not have TB. This is consistent with the findings of several studies that measured the QOL of adult caregivers whose children suffered from chronic diseases such as osteogenesis imperfecta (Vanz et al., 2015), sickle cell disease (van den Tweel, 2009), cancer (Rubira et al., 2012; Sajjadi et al., 2013), disabilities, Down's syndrome (Bain & Hoon, 2015), speech and language disorders (Zerbeto & Chun, 2013), COPD (Kumar et al., 2012), and schizophrenia (Panigrahi et al., 2014). All these studies revealed that the caregivers of the diseased children had impaired QOL compared with control populations. Findings from inferential statistics revealed that all three research questions have been answered as explained in the following section, which presents the

interpretation of the findings of the main study, relationship of findings to theoretical framework, limitations of the study, recommendations, study implications for positive social change, and a conclusion.

Interpretation of the Findings

The findings of the three research questions can be interpreted as follows:

Research Question 1

RQ1: Is caregivers' QOL related to the reporting of CTB?

Ho1: Caregivers' QOL is not related to the reporting of CTB.

Ha1: Caregivers' QOL is related to the reporting of CTB.

As recommended by the WHO (1994), caregivers' QOL was measured broadly in the context of their physical health, psychological state, social relationships, and their relationship to salient features of their environment, using the WHOQOL-BREF questionnaire. The data obtained was subjected to the MLR test with the help of SPSS software. The results of the MLR test confirmed a statistically significant relationship between caregivers' QOL and the reporting of CTB. This is especially true for two out of the four QOL domain variables, the transformed social relationships summed score, TSRSS, ($p < .01$; adjusted OR 1.20) and the transformed environmental summed score, TEnviroSS ($p < .001$; adjusted OR 0.65). Furthermore, since the adjusted OR is > 1 , then it can be concluded that the group of caregivers whose children do not have TB have higher levels of satisfaction with their lives (especially regarding social relationships and the environment) than the group of caregivers whose children have TB, thereby rejecting the null hypothesis.

These findings correspond with the outcome of studies that established a statistically significant relationship between caregivers' QOL and the occurrence of other chronic diseases in their children (Bain & Hoon, 2015; Kumar et al., 2012; Panigrahi et al., 2014; Rubira et al., 2012; Sajjadi et al., 2013; van den Tweel, 2009; Vanz et al., 2015; Zerbeto & Chun, 2013). All these studies revealed that the caregivers of the diseased children had impaired QOL compared with the control populations.

Research Question 2

RQ2: Is caregivers' gender related to the reporting of CTB?

Ho₂: Caregivers' gender is not related to the reporting of CTB.

Ha₂: Caregivers' gender is related to the reporting of CTB.

Results for this research question showed that the adjusted OR is 0.855 and the 95% confidence interval is .220 to 3.326. Although this signifies that some relationship exist between the gender of caregivers and the reporting of TB in their children, the relationship is however not statistically significant because the *p* value is $>.05$ and the confidence interval includes 1. Thus, it can be concluded that the relationship between caregivers' gender and the reporting of CTB is not statistically significant and therefore the null hypothesis cannot be rejected.

Several studies have established that more females are involved in caregiving of children with chronic illnesses than males (Kumar et al., 2012; Vanz et al., 2015). However, this study revealed that, in both groups, there were more men involved in the caregiving of children with TB than females, but this gender differences was not significantly related to the reporting of CTB because the *p* value is $>.05$. In other words,

the presence or absence of TB in a child may not necessarily be related to his or her caregivers' gender. More studies are needed to determine if there are gender differences in caregiving of children with TB.

Research Question 3

RQ3: Is caregivers' SES related to the reporting of CTB?

Ho₃: Caregivers' SES is not related to the reporting of CTB.

Ha₃: Caregivers' SES is related to the reporting of CTB.

Results from the analysis indicated that caregivers' SES, as measured by their educational status, is not related to the reporting of TB in their children because $p > 0.05$. However, as shown earlier, caregivers whose children had TB were less educated than those whose children had no TB. The more educated caregivers in the latter group may have better jobs with higher incomes, higher standards of living and their children's health may likely be above average (Zimmerman, Woolf, & Haley, 2015). In this respect, it can be argued that caregivers' SES is inversely related to the reporting of TB in their children. However, educational status alone is not a sole measure of the SES but part of a continuum of variables used by researchers to measure it. For instance, the Brazilian Association of Research Companies Economic Classification Criterion and the WAMI index are two separate tools used respectively by Vanz et al. (2015) and Psaki et al. (2014) to measure the SES of adult caregivers of children whose children suffered from chronic illnesses in resource limited settings.

The Entire Study Model

Interestingly, when the MLR test was done on the entire study model containing all the independent variables (see figure 4), a statistically significant relationship was established: $\chi^2 (9, N = 94) = 72.398, p < .001$. This suggested that the combined variables of caregivers' QOL, gender and SES (education) were related to the reporting of CTB and the relationship was statistically significant, thereby rejecting the null hypothesis. In other words, the combined effects of caregivers' QOL, gender and SES (education) were found to be significantly related to the reporting of TB in their children.

The finding of a statistically significant relationship in the combined model and not in the individual variables in research questions 2 and 3 may be explained using the principle of statistical interaction (Field, 2013). The effect of one independent variable may depend on the level of the others, and so its main effect may not be sufficient to produce a statistically significant relationship with the dependent variable. In such situations, when these independent variables are crossed with one another, such as in this case, a sufficient cumulative effect necessary to establish a statistically significant relationship with the dependent variable was produced.

Relationship of Findings to Theoretical Framework

This study was guided by the TRA/TPB theoretical framework in view of its established role in predicting health behavior in humans as demonstrated by Conner and Norman (2005). In the same way Saleh (2014) was guided by the TPB to study neonatal tetanus (NNT), a vaccine preventable disease, in Northeastern Nigeria, I was also guided

by the same TPB to study childhood tuberculosis (CTB), another vaccine preventable disease in the same region.

Expectedly, all the three constructs of this framework could explain the finding of my study. The caregivers' attitude, subjective norm and perceived behavioral control which determine their behavioral intentions (BI) towards performing a particular health related behavior (Glanz et al., 2008) could explain the study's finding of a statistically significant relationship between their QOL and the reporting of CTB. Those with positive attitudes, subjective norm and perceived behavioral control are likely going to have higher QOL and children without TB, while those with negative constructs are likely going to have lower QOL and children with TB. Caregivers with higher QOL are more likely to be healthier, free from any infectious illnesses transmissible to their children, such as TB, as such their children are more likely to be healthier, free from TB, than those of caregivers with lower QOL. Thus, the reporting of CTB may be more pronounced in the latter group than in the former.

Thus, the TPB was a valid framework to use for this study since it could explain the key findings of the study. However, it was not without some limitations: it could not account for other external variables that could affect the caregivers' behavioral intentions such as availability of resources, physical fear, known and unknown threats, mood changes and past experiences both desirable and undesirable (LaMorte, 2016). LaMorte (2016) opined that although these environmental and economic variables may influence peoples' intentions to perform a health related behavior, they are beyond the control of the TPB.

Limitations of the Study

The first limitation of this study that comes to mind is the fact that the study was undertaken only in Bauchi State, one out of the 37 states of Nigeria, yet its findings were meant to be generalizable to the entire Nigerian population. Due to obstacles posed by high cost, inadequate logistics and time, the author could only afford to conduct the study in only one out of the 37 states of Nigeria. However, the high response rate recorded would have reduced the threat to generalizability of the findings.

Other limitations of this study are those inherent in cross sectional designs such as selection and information (interviewer) biases as well as confounding (Frankfort-Nachmias & Nachmias, 2008). The former was controlled through randomization of the study participants while the latter was controlled because I interviewed all the study participants face to face using a standard valid tool, the WHOQOL-BREF questionnaire, thereby reducing differential misclassification to the barest minimum (Frankfort-Nachmias & Nachmias, 2008). Confounding was controlled by matching the age and gender of each child with TB with another child without TB (Pourhoseingholi et al., 2012). This ensured that the study participants do not differ significantly with respect to possible confounders of age and gender.

My inability to conduct a pilot study as I had planned in the research protocol could be considered as another limitation of the study. Apart from the fact that I was constrained with time and resources, I also reasoned that the study tools I chose to use are standard and validated instruments already. The WHOQOL-BREF questionnaire is a standard and valid tool that has been adjudged globally to measure exactly what it is

intended to measure, the QOL of the study population (WHOQOL, 1994). The other two instruments, appendix B and C were adapted from previous peer reviewed research studies on CTB and were reproduced with permission from the copyrighted owners. Consequently, lack of the pilot study may not have any negative impact on the validity of the study findings. In any case, conducting a pilot study successfully is not a guarantee of the success of the full-scale survey, and where an established and validated tool (s) is being used, it could be argued that such data may be of value (van Teijlingen & Hundley, 2001).

Lastly, I must mention a very important limitation of this study, which is the use of educational status of respondents as a sole measure of their SES. It is a known fact that SES is measured using several other variables such as income, occupation, access to improved water and sanitation and household wealth/assets (Psaki et al., 2014; Vanz et al., 2015). However, the WHOQOL-BREF questionnaire contains only one (education) out of these variables. I was therefore constrained to use only education as a sole measure of the SES of the respondents. With the benefit of hindsight, I ought to have used an additional questionnaire to measure the participants' SES such as the Brazilian Association of Research Companies Economic Classification Criterion used by Vanz et al. (2015), or the WAMI index used by Psaki et al. (2014) to measure the SES of adult caregivers of children whose children suffered from chronic illnesses.

Recommendations

Recommendations for Action

The outcome of this study is recommended for community leaders, TB program officers at all levels, Nigerian public health authorities, policy makers and researchers. Evidence from this study suggests that the reporting of TB in children aged 0-14 years is significantly related to the QOL of their caregivers. Thus, the QOL of women of child bearing age, parents and other caregivers should be improved, since this would have a direct relationship to the well-being of their children. This is even more expedient given the patriarchal nature of our society, where men tend to dominate over women in all aspects of life (Patowary, 2014). Improving the QOL of women in a patriarchal society entails giving them proper atmosphere where they can voice their opinions against inequalities and the gender-gap they are going through as well as improving their status in every aspect (Patowary, 2014).

Moreover, improvement in the QOL of caregivers would involve multiple sectors other than health such as food security, housing, security of lives and property, provision of clean drinking water, qualitative education, and creation of jobs. Clearly, these are responsibilities of policy makers holding political offices. For the health sector, public health authorities should give priority attention to health promotion activities, preventative and curative health care services.

Using TB as an example, health promotion services would include awareness creation about TB, its causes, transmission, and treatment and where to obtain such services. Preventive services would include provision of good housing to avoid

overcrowding, personal hygiene including cough etiquette, and immunization of all newborn babies with the BCG. Curative services would include the detection, investigation, confirmation of diagnosis and commencement of treatment so as to achieve complete cure, thereby halting the transmission of the infection within families and communities. Preventative and curative health care services are mainly the responsibility of TB program officers at all levels.

The community should be involved in reducing child morbidity and mortality due to TB through the building of partnerships and community structures such that: all pregnant women attend antenatal and post-natal care services available at their doorsteps; all sick children aged 0-14 years should be taken to the nearest health center for proper medical attention. Lastly, researchers should come up with more evidence based innovative approaches to detect and treat all possible CTB cases out there in the community.

Recommendations for Future Research

In view of the multiethnic and multicultural nature of Nigeria, future research studies should be replicated in other parts of Nigeria in order to determine if findings would differ between one region/state to the other. Second, this study should be repeated with an additional validated tool that measures SES such as the tool developed by Psaki et al. (2014) in measuring SES across diverse, resource-limited settings like Nigeria. Apart from maternal education, the WAMI index has incorporated several aspects of SES such as access to improved water and sanitation, household wealth (assets), and income. Another tool that measures SES, which could be used for future studies, is the one used

by Vanz et al. (2015) in measuring the SES of caregivers whose children suffered from Osteogenesis Imperfecta (OI) in Brazil. Lastly future studies should be longitudinal in nature and should aim at bigger sample sizes since, with large sample sizes, MLR tends to give more statistically significant results that enable researchers to reject the null hypothesis (Williams, 2015; Knoke & Mundfrom, 2008).

Study Implications

Several research studies have measured the QOL of caregivers whose children suffered from chronic diseases (Bain & Hoon, 2015; Kumar et al., 2012; Panigrahi et al., 2014; Rubira et al., 2012; Sajjadi et al., 2013; Vanz et al., 2015; Zerbeto & Chun, 2013) and found out that it was impaired relative to that of the control populations, thus establishing statistically significant relationships between caregivers' QOL and the occurrence of such chronic childhood diseases. However, such studies have not been carried out with caregivers of CTB cases, in spite of the fact that TB is a disease of public health importance (WHO, 2015a), and children are often neglected in virtually all aspects of the response to the TB epidemic (Daniel et al., 2015; Erkens et al., 2014; Hamzaoui et al., 2014; Swaminathan & Rekha, 2010; WHO, 2013a). Hence this study was undertaken in Bauchi State, northeastern Nigeria, with the sole purpose of exploring the possible relationship between the QOL, gender and SES of adult caregivers and the reporting of TB in their children aged 0-14 years.

Although the study found a statistically significant relationship between the caregivers' QOL and reporting of TB in their children (research question 1), the caregivers' gender and SES (research questions 2 and 3 respectively) were not

significantly related to the reporting of TB in their children. Interestingly, the combined study model containing all the three independent variables showed a statistically significant relationship with the dependent variable at $p < .001$. Thus, with the findings in research question 1 and the combined model, it can be inferred that the QOL of caregivers whose children suffered from TB was impaired compared with that of caregivers whose children did not suffer from TB. It can further be stated that the study's research questions have been answered and the objectives achieved, thereby filling the earlier identified research gap of paucity of information on QOL of caregivers of children affected by TB in Nigeria. However, there is a need for additional information on the caregivers' knowledge and skills, including their personalities and dispositions, which may be better obtained through qualitative operational research studies.

Lastly, the study findings have implications for medical personnel, public health authorities, researchers and policy makers. In the management of CTB cases, medical personnel, including Doctors, should be conscious of the emotional and functional needs of the children's caregivers. Improved support may be needed to enhance the QOL of both the children with TB and their caregivers.

The public health authorities at all levels should ensure that medical personnel change the course of caregiving by respecting the role caregivers play in managing ongoing care beyond the classic boundaries of professional patient care. They should ensure that medical personnel move away from the traditional "expert model of service delivery" to a newer model recommended by Reinhard, Given, Petlick, and Bemis (2008) that involves the triad of the patient, caregiver and the medical personnel. In this model

of caregiving, the medical service provider interacts with and assists not only the patients but the informal caregiver as well. This approach has the potential of increasing the caregivers' feelings of control over health, QOL and compliance with prescribed medications.

Researchers should not only concentrate on examining caregiver-patient relationship but should also explore the nature of the knowledge and skills of the caregiver, including their personalities and dispositions. Policy makers should provide an enabling environment for all stakeholders, both governmental, non-governmental and development partners to work harder, and in partnership, towards improving the QOL of caregivers of young children, including women of child bearing age. This would go a long way in having a positive impact on the overall wellbeing of their children. Finally, policy makers and those in the position of authority should strive to empower caregivers economically as a way of directly improving their QOL and indirectly that of their children, both healthy and ill. In this way, the finding of this study would have contributed to positive social change at individual, family, community and societal levels.

Conclusion

Children accounted for 10% of the total global TB burden in 2015, which translated to an estimated 1.0 million cases and 210,000 deaths, yet they remain neglected relative to adults, in all aspects of the global responses to the TB epidemic, including research (WHO, 2016a). There is paucity of research studies examining the relationship between the reporting of CTB and variables pertinent to caregivers of young children in

Nigeria. Hence the need for this study, undertaken in Bauchi State, northeastern Nigeria, for the period January 1, 2011 to December 31, 2015.

Although the study found a statistically significant relationship between the caregivers' QOL and reporting of TB in their children (research question 1), the caregivers' gender and SES (research questions 2 and 3 respectively) were not significantly related to the reporting of TB in their children. Interestingly, the combined study model containing all the three independent variables showed a statistically significant relationship with the dependent variable at $p < .001$. Therefore, the required evidence for all stakeholders to put all hands on deck towards improving the QOL of caregivers, including empowering them socio-economically as a panacea for the prevention and control of TB in their children may have been found. More research is needed with an appropriate tool to measure caregivers' SES and relate it with the reporting of CTB.

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Appendix A: List of Health Facilities in the Three Selected LGAs

S/N	Katagum LGA	Misau LGA	Bauchi LGA
1	FMC Azare	GH Misau	ATBUTH
2	Ragwam PHC	PHC Hardawa	IDH Bayara
3	Gwasmai	GH Akuyam	T/Babiye
4	Yayu	PHC Garam	Urban Martenity
5	Madara	PHC Gaina Hausa	M/katagum
6	Buskuri	PHC Zadawa	PHC Tirwin
7	Matsango	PHC Shelan	PHC Durum
8	Gambaki	MCH Misau	MCH Bayan Fada
9	Bulkachuwa	PHC Madari	PHC Kangere
10	Chinade	PHC Dunkwi Kasuwa	Alamin clinic
11	Shifaa		Tudun Gambo
12	Urban Maternity		Fed lowcost
13	Kastelle		MCH Wunti Dada
14	GH Hospital Azare		PHC L/Katagum
15	Amana clinic		Amsad clinic
16	Hamdala clinic		Yelwa Dom
17	Ardo clinic		PHC Luda
18			Reemee clinic
19			Shadawanka
20			Bauchi prison
21			State lowcost
22			PHC K/Dumi
23			Shifa clinic
24			Apple clinic
25			PHC Buzaye
26			COCIN Clinic

27			El-Wadata
28			PHC Gudum Hausawa
29			Niima clinic
30			Rahama clinic
31			Alheri clinic
32			Jamaa clinic
33			Police clinic
34			School of armour clinic
35			PHC Baram
36			AL-Amin clinic Inkil
37			Phalycon clinic
38			Specialist Hospital Bauchi
39			Yelwa Clinic

Appendix B: Number of All Childhood TB Cases Notified

Zone:																			
LGA:																			
Facility:																			
Year:																			
S/ N	2011			S/ N	2012			S/ N	2013			S/ N	2014			S/ N	2015		
	LGA TB ID NO:	DOB	Se x		LG AT B ID NO:	DOB	Sex		LGA TB ID NO:	DOB	Se x		LGA TB ID NO:	DOB	Se x		LGA TB ID NO:	DOB	Sex
1				1				1				1				1			
2				2				2				2				2			
3				3				3				3				3			
4				4				4				4				4			
5				5				5				5				5			
6				6				6				6				6			
7				7				7				7				7			
8				8				8				8				8			
9				9				9				9				9			
10				10				10				10				10			
11				11				11				11				11			
12				12				12				12				12			
13				13				13				13				13			
14				14				14				14				14			
15				15				15				15				15			
16				16				16				16				16			
17				17				17				17				17			
18				18				18				18				18			
19				19				19				19				19			
20				20				20				20				20			

Note. SN = serial number. LGA TB ID NO = Local Government Area TB Identification Number. DOB = date of birth.

Adapted from “Prevalence of neonatal tetanus in Northeastern Nigeria” J.A. Saleh (2014). *Walden University Scholar Works: Dissertations and Doctoral Studies*, p. 130. Reproduced with permission.

Appendix C: Summary of the Extracted Childhood TB cases

Zone	LGA	Facility	2011	2012	2013	2014	2015	Total
Northern	Katagum	FMC Azare						
		GH Azare						
		Bulkachuwa						
Central	Misau	GH Misau						
		Hardawa						
Southern	Bauchi	ATBUTH						
		IDH Bayara						
		T/Babiye						

Note. SN = serial number. CTB = childhood TB. DOB = date of birth. Q1 = quarter one
Adapted from “Improving the estimates of childhood TB disease burden and assessing
childhood TB activities at country level” A. Detjen, et al. (2012). Retrieved from
http://www.challengetb.org/publications/tools/hss/Improving_the_estimates_of_childhood_TB.pdf, p.16. Reproduced with permission.

Appendix D: Permission to Use WHOQOL-BREF Questionnaire

From: whoqol

Sent: Wednesday, April 13, 2016 1:47 PM

To: ADAMU, Haruna Ismaila

Subject: RE: Request for a copy of WHOQOL-BREF questionnaire and permission to use it for my PhD dissertation.

Dear Dr Adamu,

Thank you for your interest in the WHOQOL-BREF. Please contact our U.S. collaborators (seaqol@u.washington.edu) or go to the following website for more information on how to obtain the American English version of the questionnaire:
<http://depts.washington.edu/seaqol/WHOQOL-BREF>

Sibel Volkan (Mrs)

WHOQOL

Information Evidence and Research (IER) Department

The World Health Organization

20 Avenue Appia

CH-1211 Geneva 27

Switzerland

Appendix E: Permission to Reproduce WHO Copyrighted Material

ID: 210829 Permission authorization for WHO copyrighted material

permissions@who.int

Dear Dr Adamu

Thank you for your request for permission to reprint and reproduce certain WHO copyrighted material.

On behalf of the World Health Organization, we are pleased to authorize your request to reproduce the WHO materials as detailed in the form below, subject to the terms and conditions of the non-exclusive licence below.

If you have questions regarding this authorization, please contact permissions@who.int.

We thank you for your interest in WHO published materials.

Kind regards,
WHO Permissions team

Appendix F: Invitation to Participate in Research

Date.....

Dear Participant,

I am pleased to inform you that I have obtained an approval from Bauchi State Ministry of Health's Research Ethics Committee (HREC) and Walden University's Institutional Review Board (IRB) for ethical standards in research to collect data for my research project entitled "Relationship between Caregivers Quality of Life and Childhood Tuberculosis in Nigeria".

You are therefore cordially invited to participate in this important research project.

Your participation in this research study is entirely voluntary. It is your choice whether to participate or not. *For more information about the study, please kindly refer to the attached consent form which provides more details about the study.*

Should you decide to participate, kindly indicate below the day, time and venue of your choice for a face to face interview with you. For instance, the day could be any day of the week from Monday to Sunday between 8 am to 5 pm in the month of February 2017. The venue for the interview could be a neutral and private place in your community such as a private room in the community center, health center or school.

Date.....

Venue.....

Time.....

Please kindly mail your response to me using the enclosed self-addressed and stamped envelope at your convenience. Should you have any questions or clarifications, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

Haruna Adamu
No. 20, Abdulkadir Ahmed Street, Bauchi, Nigeria.
Tel: 08035978458,
Email: drharuna.adamu@waldenu.edu

Appendix G: Permission to Gain Access to Childhood TB Data

SECRET



GOVERNMENT OF BAUCHI STATE

MINISTRY OF HEALTH

Bello Kirfi Road, Off Murtala Mohammed Way,
P.M.B. 065, Bauchi.

E-mail: bauchismoh@gmail.com

MOH/GEN/S/1409/I

28th October 2016

Reference.....

Date.....

PROTOCOL APPROVAL NO: NREC/12/05/2013/16/43

Dr Adamu Haruna Isma'il,
WHO NPO/TUB-NEZ,
UN Premises,
Bauchi.

ETHICAL CLEARANCE FOR SUBMITTED PROTOCOL: "Relationship Between Caregivers Quality of Life and Childhood TB in Bauchi State- Nigeria"

The Bauchi State Health Research Ethics Committee (HREC) under the State Ministry of Health has received the above named protocol for ethical clearance and approval in line with the guidelines set by the Committee. The protocol was reviewed and the committee noted that the research falls under the low risk Category which does not entails clinical trials or any invasive procedures.

2. Consequently, the Committee has granted approval for the research to be conducted. However, you should share with us your workplan clearly indicating the start date, where and when to visit the research site(s) and also **the final results of your findings**.

3. The Committee requires you to comply with all Institutional Guidelines, Rules and Regulations and with the tenets of the National Health Research Ethics Committee Code including that all adverse events are reported promptly to the Committee. **No changes are permitted in the research without prior approval by the Committee** except in circumstances outlined in the Code. The Committee reserves the right to conduct compliance visit to your research site without prior notice.

4. Thank you.

(Usman U. Muhammad)
For: Hon. Commissioner.

Appendix H: Permission to Use Data Collection Instrument B

Jalal Saleh, PhD <drjadeen@gmail.com>
to me, haruna

Dear Dr. Adamu,

I refer to your email request to reproduce and modify the tool I used in my PhD dissertation.

Kindly go ahead and use the tool for the sole purpose of your PhD dissertation.

Best of luck in your research work.

Jalal

Jalal Saleh, PhD, MD,
NPO - Malaria (NWZ),
World Health Organization,
Kano Zonal Office,
Kano, Nigeria.
Email: salehj@who.int
Skype: drjadeen

Appendix I: Permission to Use Data Collection Instrument C

Anne Detjen <adetjen@unicef.org>
to me

Dear Haruna, sure, you are welcome to use the table!
I'd be curious to see the results of your work – would you mind sharing when you're done?

Good luck, Anne

Dr. Anne Detjen

Health Specialist, Childhood TB
United Nations Children's Fund (UNICEF)
3 UN Plaza
New York, NY 10017
Office +1 212 326 7394 | mobile +1 646 919 5204
Email adetjen@unicef.org | skype anne.detjen

Follow us on [Facebook](#), [Twitter](#), [YouTube](#) and at www.unicef.org

Appendix J: IRB Approval

Dear Mr. Haruna,

This email is to notify you that the Institutional Review Board (IRB) has approved your application for the study entitled, "**Relationship between Caregivers Quality of Life and Childhood Tuberculosis in Nigeria.**"

Your approval # is 02-10-17-0427198. You will need to reference this number in your dissertation and in any future funding or publication submissions. Also attached to this e-mail is the IRB approved consent form. Please note, if this is already in an on-line format, you will need to update that consent document to include the IRB approval number and expiration date.

Your IRB approval expires on February 9th, 2018. One month before this expiration date, you will be sent a Continuing Review Form, which must be submitted if you wish to collect data beyond the approval expiration date.

Your IRB approval is contingent upon your adherence to the exact procedures described in the final version of the IRB application document that has been submitted as of this date. This includes maintaining your current status with the university. Your IRB approval is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, your IRB approval is suspended. Absolutely NO participant recruitment or data collection may occur while a student is not actively enrolled.

If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB application, you made a commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden website: <http://academicguides.waldenu.edu/researchcenter/orec>

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Best,

Bryn Saunders

Research Ethics Support Specialist

Office of Research Ethics and Compliance

Email: irb@mail.waldenu.edu

Walden University

100 Washington Avenue South, Suite 900

Minneapolis, MN 55401 Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link: <http://academicguides.waldenu.edu/researchcenter/orec>

Appendix K: Permission to reproduce NTBLCP Materials

kuye Joseph <kuyeoj@hotmail.com>
to haruna, oluwadarasimi22, me

Dear Dr. Haruna

I hope my mail meets you well

I have been directed by the National Coordinator of the NTBLCP to inform you that you have the permission of the NTBLCP to reproduce the content of the said materials as requested.

Regards

For the NC, NTBLCP

Appendix L: Permission to Reproduce Figure 3

Ben Marais (SCHN) <ben.marais@health.nsw.gov.au>
to me, haruna

Dear Haruna

Please feel free to use – acknowledging the relevant reference.

Good luck with finalizing your dissertation.

Regards

B

Professor Ben J Marais

Infectious Diseases Clinician, The Children's Hospital at Westmead

Deputy Director, Marie Bashir Institute for Infectious Diseases and Biosecurity (MBI)

Centre for Research Excellence in Tuberculosis (TB-CRE)

UNIVERSITY OF SYDNEY

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www.tbcre.org.au

www.sydney.edu.au/mbi